

This document has been superseded by the FDA FY 2000 Performance Plan. Final FY 1999 performance commitments are found in Appendix 2 of the FY 2000 plan.

**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

**Fiscal Year
1999**

Food and Drug Administration

Performance Plan

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Note on printing the plan: This document is divided into several sections. Each can be printed separately. The entire text of Part I, Introduction to Budget and Program Summaries, and the FY 1999 Program Resource Summary can be printed together. To print the program summaries, navigate to each section and then print. (Tobacco, Imports, and External Leverage are combined in one file.)

Introduction to the Food and Drug Administration's FY 1999 Performance Plan

This document is a management window into the FDA, an agency that affects every American every day. In this performance plan, FDA proposes very specific goals to carry out its mission in Fiscal Year (FY) 1999. These goals commit FDA to:

making foods safe and free of contamination;

giving consumers faster access to important new drugs and therapies;

protecting youth from the deadly effects of smoking; and

expanding partnerships that help improve the nation's disease surveillance, cancer screening, scientific research, labeling and self-regulation of foods and drugs.

The uses of the FY 1999 Performance Plan are many. For example:

Congress will use this plan to understand the relationship between program intentions and requested appropriations.

Government managers in other Federal, state and local health agencies will use this plan to develop and refine the network of partnerships in which they participate with FDA to protect the public health.

Corporate managers in the affected industries will use the plan to develop complementary industry efforts to improve product quality and to optimize new product development plans.

FDA managers will use this plan to focus on results and to develop improved processes to accomplish goals more cost-effectively.

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Layout of the Plan

Part I: Overview

The [FDA Mission Statement](#), from Public Law (PL) 105-115.

[Linkage to the Mission and Strategic Plan of DHHS](#).

The four [Key Performance Commitments](#) indicate that food safety, drug and medical device approval, tobacco use among youth, and partnerships for health protection will be some of FDA's most important outcome-oriented goals for FY 1999.

The [Programs](#) indicate how FDA's resources are organized.

The [Strategic Framework](#) summarizes the overall structure and strategies for conduct of the Plan. It focuses all Agency programs on results-oriented goals described by GPRA. [1]

The [Measuring, Monitoring and Reporting on Results](#) pages discuss the task of FDA's verifying and validating the goals -- and monitoring how well they are being accomplished.

Part II: Budget and Program Summaries

The [Introduction to Part II](#) indicates how the FDA program narratives are arranged within FDA's Performance Plan.

Program Goal Summaries: The last section of the Performance Plan is arranged by FDA program area, and provide information about each program's proposed goals for FY 1999 that includes:

FY 1999 Resources: Anticipated costs and for programs and personnel

Strategic Future: Facts and insights into emerging issues

Clusters: The most closely related performance goals

Performance Goals: Specific accomplishments the agency plans for the year

Performance Measurement: Guidelines for determining when results are achieved

1. FDA's FY 1999 Performance Plan is part of a government-wide effort to hold agencies accountable for achieving results. In 1993, with passage of the Government Performance and Results Act (GPRA), Congress directed all Federal agencies to adopt more businesslike management approaches. This reflected a new commitment to reducing costs and improving performance. FDA's 1999 Performance Plan represents an important step toward enhancing its record of public health improvement, while at the same time providing a cost-effective value for American taxpayers.

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FDA Mission

In 1997, for the first time in history, Congress codified FDA's mission statement into law (Public Law 105-115). This new mission not only addresses the specific public health responsibilities such as those relating to food and drug safety, but it also emphasizes the manner in which those responsibilities will be carried out, such as through collaboration with consumers, manufacturers, importers and retailers of regulated products.

Mission of the Food and Drug Administration

1. To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
2. With respect to such products, protect the public health by ensuring that:
 - o foods are safe, wholesome, sanitary, and properly labeled;
 - o human and veterinary drugs are safe and effective;
 - o there is reasonable assurance of the safety and effectiveness of devices intended for human use;
 - o cosmetics are safe and properly labeled, and;
 - o public health and safety are protected from electronic product radiation.
3. Participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
4. As determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with

experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors and retailers of regulated products.

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Linkage to Department of Health and Human Services Mission and Strategic Plan

FDA's FY 1999 Performance Plan carries out the mission of its parent agency, the Department of Health and Human Services (DHHS). The DHHS mission is:

"To enhance the well-being and health of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health and social services."

The FDA plan also puts into action the goals and objectives set forth by the [DHHS strategic plan](#). FDA is committed to the following five strategic objectives that are included in the DHHS plan:

1. Assure food and drug safety by increasing the effectiveness of science-based regulation.
2. Accelerate private-sector development of new drugs, biologics, therapies, and medical technology.
3. Reduce tobacco use, especially among youth.
4. Improve the diet and level of physical activity of Americans.
5. Promote the appropriate use of effective health services.

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FDA's Key Performance Commitments

The next section highlights FDA's most important performance commitments relating to its mission: food safety, premarket review, tobacco, and partnerships. These four commitments, coupled with the Agency's performance goals, budget priorities, and program areas outlined later in this plan, support the new mission. And even though the ultimate outcomes may not be achieved until after 1999, they represent the Agency's highest priorities during FY 1999.

Key Performance Commitment #1

Food Safety Initiatives

Outcome: Reduce illness associated with microbial contamination of

foods.

**Background
and
Strategy:**

Although the U.S. food supply is one of the safest in the world, the increasing number of reported foodborne illnesses threaten public health. Available estimates of foodborne illnesses run into the millions, with thousands of deaths every year. Causes of these illnesses range from a lack of knowledge about safe food handling practices, to physiological changes in microorganisms, to changes in the food supply and its distribution, to an increasing number of consumers vulnerable to foodborne illnesses because of their compromised health status. Some previously harmless microbes are now causing diseases, and some are even developing resistance to traditional medical treatments or to techniques used to prevent their growth in food.

As part of the interagency Food Safety Initiatives, FDA is working with USDA, CDC, EPA, international groups, states, consumers, academia and industry to improve the safety of the food supply. Key components of this integrated effort include targeting the most pressing microbial public health hazards; quickly identifying foodborne illness outbreaks; improving food inspections; and educating consumers, industry, and health professionals. This initiative will also emphasize surveillance for foodborne illness, risk assessment, research, and improved coordination and communication to rapidly deal with emerging public health hazards.

**Key FY 1999
Performance
Goals:**

- Develop improved baseline surveillance data of foodborne illness.
- Reduce the prevalence of reported risky food consumption behaviors.
- Reduce the prevalence of reported risky food preparation practices.
- Assure that 50 percent of the seafood industry is operating under appropriate hazard assessment and control systems (Hazard Analysis and Critical Control Point - HACCP).
- Begin implementing HACCP systems in the juice industry.
- Achieve adoption of the Food Code by 25 percent of states.
- Assure that 40 percent of domestic produce is grown and processed using good agricultural and manufacturing practice guidance for minimizing microbial contamination.
- Develop scientific methods for minimizing microbial contamination on fresh produce.
- Study factors that cause foodborne pathogens to develop multiple antibiotic resistance and resistance to traditional food preservation techniques.

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Key Performance Commitment #2

Premarket Review

Outcomes: Reduce the time required to bring important new drugs to the public; and,
Improve public access to important new medical devices, vaccines, and food additives.

Background and Strategy: FDA has the responsibility to assure that all drugs used in the prevention, diagnosis and treatment of disease are safe, effective and properly labeled. In order to do this, important new drugs must reach the American public as quickly as possible. Last year, approximately 11 million Americans received newly marketed drugs that would not have been available until 1998 without passage of the Prescription Drug User Fee Act that expanded FDA's capacity to speed the review process.
In order to bring important drugs, medical devices, and food additives to market quickly and safely, FDA will commit to: increasing the number of early consultations with product manufacturers; upgrading communications technologies that will expedite new product applications; and accelerating the review of products that will improve Americans' health. Harmonizing this overall effort with international drug, medical device, and food additive manufacturers has also become an important strategy for improving product safety. Through earlier and more cooperative interaction with FDA, industry representatives have indicated the possibility of a year reduction in the time necessary to bring drugs to the market.

Key FY 1999 Performance Goals: Act on 90 percent of priority new drug applications within 6 months of submission.
Act on 90 percent of priority biological (e.g. blood, vaccines, therapeutics) applications within 6 months of submission.
Act on 60 percent of original generic drug applications within 6 months of submission.
Act on 50 percent of important new medical device applications within 6 months of submission.
Act on 30 percent of direct food additive petitions within 12 months.
Continue to move toward paperless, electronic submission of drug applications.

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Key Performance Commitment #3

Tobacco

Outcome: Substantially reduce youth smoking.

Background and Strategy: Each day approximately 3,000 young people become regular smokers. In fact, 34 percent of high school students smoke cigarettes. The cost of direct medical care for tobacco-related illness is estimated at \$50 billion a year. Research shows that reducing the rate of tobacco use will improve the health and quality of life across America. FDA now has authority to regulate the use of cigarettes and smokeless tobacco as delivery devices for the drug nicotine.

In cooperation with the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA), FDA has committed to controlling tobacco use. In support of the goal of reducing youth smoking by 50 percent by the year 2003, FDA will implement and oversee enforcement of the regulation that restricts access and marketing of tobacco products to minors. With its public and private partners, FDA will educate, monitor, and enforce several strategies to achieve this outcome.

**Key FY 1999
Performance
Goals:**

Conduct an average of 42,000 unannounced compliance checks each month of retail establishments that sell tobacco products.

Educate retailers and other stakeholders about the FDA tobacco rules through a multimedia campaign including point-of-purchase, radio, outdoor advertising, and newspapers.

Design and implement a regulatory program for cigarettes and smokeless tobacco products.

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Key Performance Commitment #4

Partnerships for Health Protection

Outcome: Launch a more effective national response to public health risks through partnerships and shared responsibilities.

**Background
and
Strategy:**

Americans are among the healthiest people in the world. But we do not live in isolation. Each neighborhood, town, city, and region is affected every day by movement of people, products, and ideas that may have originated anywhere in the world. As a result, FDA is changing how it will protect consumers and promote the public health in the 21st Century.

In FY 1999, FDA will collaborate with and rely on outside parties for the management of health and safety risks to a much greater extent than ever before. FDA will use its regulatory partners, health care delivery institutions, the regulated industry, and the consumer as "multipliers" of risk management. The performance goals outlined below for FY 1999 demonstrate how the Agency is making strides in collaborative health protection by working closely with consumers, states, other Federal agencies, and international organizations.

Key FY 1999 Performance With *consumers'* help, increase public understanding of food and drug labeling.

Goals:

85 percent of adults will use food labels to make nutritious food selections.

Continue to improve the legibility and clarity of over-the-counter drug labels.

With *state partners*, improve compliance with quality health regulatory standards.

Ensure that at least 97 percent of mammography

centers meet key inspection standards.

Expand State Partnership Agreements to at least one per state to improve Federal- state coordination on health issues.

Ensure compliance with good manufacturing practices including the new BSE (Mad CowDisease) regulation through education and inspections.

With *national and global partners*, reduce the health risks of imported products.

Directly examine 3 percent of potentially high-risk imports.

Increase percentage of imports screened within 15 minutes to 55 percent.

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FDA Programs

FDA resources are organized into seven "programs" that coincide with the organization of the President's annual budget. These programs constitute the major sections of the performance plan. Each program has some responsibility for one or more performance commitments.

Foods - The mission of the Foods program is to promote and protect the public health and economic interest by ensuring that the food supply is safe, nutritious, wholesome, and honestly labeled. The national Food Safety Initiative is FDA's newest collaborative program. The program also ensures that cosmetics are safe and properly labeled.

Human Drugs - The mission of the Human Drugs program is to ensure that all drug products used for the prevention, diagnosis, and treatment of disease are safe and effective; and that information on proper use is available to all users. FDA will work more closely with drug firms to foster industry-based quality assurance programs and raise the pledge (assurance) of safety.

Biologics - The mission of the Biologics program is to ensure the safety, potency, and effectiveness of biological products for the prevention, diagnosis, and treatment of disease. This includes blood and blood products, blood test kits, bacterial vaccines and antigens, viral vaccines, therapeutic agents, and other biological products.

Medical Devices and Radiological Health - The mission of the Medical Device and Radiological Health program is to ensure that medical devices intended for human use are safe, effective, and properly labeled; and that the public is not exposed to unnecessary radiation from medical, industrial, and consumer products. FDA will concentrate resources on high-risk, high-impact products or work areas, where direct intervention helps consumers and health professionals the most.

Animal Drugs and Feeds - The mission of the Animal Drugs and Feeds program is to ensure that only safe and effective animal drugs, devices, feeds, and food additives are marketed; and ensure that foods and food additives from animals that are administered drugs, in accordance with label directions, are safe for human consumption.

National Center for Toxicological Research - The mission of the National Center for Toxicological Research (NCTR) is to implement peer reviewed, high-quality scientific research to develop methods for regulatory applications and provide a mechanistic basis for human risk assessment as it pertains to FDA's regulatory mandate. NCTR accomplishes its mission by conducting fundamental and applied research.

Tobacco - The mission of the Tobacco program is to reduce young people's use of tobacco by the year 2003 through education, enforcement, and partnerships with the Centers for Disease Control and Prevention (CDC), and other Federal and state health agencies.

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Strategic Framework

The "strategic framework" (shown below) reflects FDA senior managers' most significant performance directions for the Agency. This framework represents key strategic directions into the 21st Century. The framework emphasizes essential elements in the FDA and DHHS missions and includes critical practices outlined in the Government Performance and Results Act (GPRA). By using this framework across the Agency, FDA has challenged itself to emphasize results instead of process goals.

Two features of this framework are important to notice. First, the four goal areas shown across the two top rows overlap with the four performance commitments that FDA has made in the FY 1999 Performance Plan. This has helped to validate the Agency's highest priorities. Second, the framework emphasizes performance improvement and risk management. For example, FDA would focus first on regulatory actions that have the potential to impact the most Americans.

| <i>Goal Area</i> | PREMARKET T REVIEW | POSTMARKET T ASSURANCE | INTERNAL CAPACITY | EXTERNAL LEVERAGE |
|-----------------------|---|---|---|--|
| <i>Goal Statement</i> | Make timely and cost effective premarket review decisions while assuring product safety and efficacy | Strengthen assurance that products on the market or about to enter the market are safe | Focus FDA's capacity for effective pre and postmarket regulatory decisions | Augment the ability of external stakeholders to manage FDA-regulated risk |
| <i>FDA Strategies</i> | Develop science-based review standards Inform and assist product sponsors Streamline reviews Focus on high priority applications Increase patient | Develop science-based product and process standards and guidance Target high priority domestic and import risks Inform and assist firms to achieve conformance Maintain inspection | Implement decision-supportive information systems Cultivate a high quality, motivated workforce Achieve greater economies in facilities | Foster industry quality assurance programs, e.g. HACCP Support U.S. interests in global standard setting Empower consumer choice through product |

| | | | | |
|--|-----------------------------------|---|--|---|
| | access to experimental therapies. | visibility Improve surveillance and follow-up on adverse events Integrate import and international harmonization activities | Refocus FDA's pre and postmarket responsibilities Consolidate and prioritize research activities Increase coordination of international harmonization activities | labeling and education Use third parties for routine reviews and compliance monitoring Collaborate with Federal and state regulators to reduce health risks Collaborate with industry in support of research Pursue public-private partnerships to expand resources |
|--|-----------------------------------|---|--|---|

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Measuring, Monitoring and Reporting on Results

FDA's approach to performance-based management consists of the following stages:

Set strategic goals and ways to achieve them (strategies);

Target annual performance goals that support both the Agency's strategies and structure;

Develop a measurement capability;

Monitor progress toward goal achievement; and

Report on results.

This approach will be used both to improve program performance within the Agency and to keep the Executive Branch and Congress informed on FDA's achievements, as required by the Government Performance and Results Act (GPRA). The Figure below illustrates the process.

Challenges in Measuring Performance:

Measuring the status of each goal will become the most critical step to knowing how well the Agency is achieving its mission. As evident from the [Strategic Framework](#) and the diverse goals included in this plan, FDA will be relying on an array of different measures to determine the organization's overall performance.

While FDA is a regulatory agency that must enforce laws and monitor compliance with the laws, the Agency has dramatically changed how it exercises this responsibility. Growing emphasis is placed on assisting the regulated industries to meet public health and safety

requirements. And this changes how FDA approaches performance measurement. On the surface, some goals may appear less challenging compared with past (baseline) performance. In reality, these goals reflect a strategic advancement by focusing on higher-risk, higher-impact responsibilities that will make the Agency more responsive to the future. With greater emphasis on outcomes, and with the establishment of more external partnerships to achieve those outcomes, agencies will depend on one another to generate useful outcome measures. Of the database examples below, the majority are not exclusively used by FDA to measure performance. Rather, they demonstrate a shift toward true results that can only be accomplished in conjunction with other institutions sharing the same public health interests.

The FDA Approach:

In 1998, FDA will initiate a system to help program managers to verify and validate performance measures. This system will have three basic components: (1) training workshops for program managers to learn the essential aspects of performance measurement; (2) a comprehensive checklist for verifying and validating performance information used to establish and monitor progress toward each goal; and (3) assistance in applying performance data as an effective management and reporting tool. This process will progressively enhance the Agency's ability to achieve and measure meaningful results.

Current Performance Measurement Efforts:

For every goal in the Performance Plan, FDA indicates what databases and baseline measures are available (or under development) to assess the goals. The Agency will use a combination of existing and newly designed databases to assess progress in achieving its goals. Many databases are collaborative efforts between other Federal and state agencies, consumer and industry groups. Some are exclusive to FDA.

The following few examples illustrate FDA's use of diverse data sources to verify and validate performance. Each of these examples relate to at least one of FDA's performance goals.

Examples of Measurement Systems:

| | |
|--------------|--|
| Tobacco | CDC's Office of Smoking and Health national survey database and the National Institute on Drug Abuse's (NIDA) Monitoring the Future Project national survey are cooperative systems that FDA will use to measure goals relating to young people's initial use of tobacco. |
| Premarket | <p>The Center-wide Oracle Management Information System (COMIS) helps ensure new drug applications are reviewed and processed within time frames established in the FY 1999 Performance Plan.</p> <p>The Compliance Status Information System (COMSTAT) is a data system for sharing FDA inspection information with foreign regulatory authorities, enabling drug manufacturers and foreign governments to expedite the marketing of new, safe and effective drugs (an important FDA goal).</p> |
| Partnerships | Operational and Administrative System for Import Support (OASIS) is an automated tracking system that helps speed safe imported products to the American people, and restrict distribution of unsafe products. This system has been designed and implemented in collaboration with the U.S. Customs Service. |

Food Safety

FDA is working with CDC and USDA to build FoodNet, a national foodborne illness active surveillance system. As part of the interagency Food Safety Initiative, this system will enable us to establish the occurrence and magnitude of foodborne illness outbreaks and allow for tracing back to the source of each outbreak.

The National Seafood HACCP Compliance Database will be used to determine how well the seafood industry is meeting the seafood safety standards and to help FDA focus training and technical assistance where needed.

FDA's Field Data System is another database for determining how well the milk, shellfish, and retail food establishments are meeting the safety/sanitation standards and provides the information that helps the industry in evaluating the effectiveness of these standards.

Through effective database management, FDA will gain important information needed to monitor progress and develop realistic future goals. As appropriate, these goals and the strategies for achieving them may be modified based on performance data.

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Introduction to Budget and Program Summaries

Part II of the plan shows the "Budget and Program Summaries" for FY 1999 that begins October 1, 1998. The resource levels requested in FDA's FY 1999 Congressional Budget will support the proposed goals described in this Performance Plan. The following section is organized in the same way as the Agency's FY 1999 Congressional Budget to allow for easy cross-referencing between the two documents. FDA provides the following information about each program's proposed goals for FY 1999, arranged in order by program areas.

FY 1999 Resources: This shows the anticipated costs and number of full-time employees (FTE) needed to accomplish the program's responsibilities.

Strategic Future: This short narrative offers readers important facts or insights into emerging issues, opportunities, or threats related to accomplishing program goals.

Clusters: FDA's programs found it helpful to combine the most closely related performance goals into several "clusters." Within most clusters you will find:

Cluster Rationale -- Why is this cluster important?

Performance Highlights -- What are the key goals?

Resources, Approaches, Process, Skills and Technology

Assumptions -- On what conditions are we basing our goals?

Performance Goals: The detailed performance goals also include supplementary information, written in a way meaningful to program managers. That information includes:

Agency strategies derived from the Strategic Framework

Data Sources for measuring progress

Baseline Data for measuring the amount of progress

Performance Measurement: FDA has developed guidelines to verify and validate its FY 1999 performance goals. These guidelines go beyond the steps of finding and generating data

related to each goal, to "knowing" that the measurement approach to each goal is valid and helpful in deciding how well the goal is being accomplished. From year-to-year this process of verifying and validating performance goals will lead to even better, more realistic outcome-oriented performance goals. As appropriate, each FDA program comments on their performance measurement strategy.

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FY 1999 PROGRAM RESOURCE SUMMARY (BY CLUSTER)

| Program/Cluster | \$000 | FTEs |
|--|----------------|--------------|
| FOODS | | |
| Food and Color Additive Review | 18,380 | 200 |
| Food Safety Assurance | 166,078 | 1,623 |
| Internal Capacity Building | 37,420 | 342 |
| Coordination | 26,839 | 278 |
| Program Total | 248,717 | 2,443 |
| HUMAN DRUGS | | |
| Premarket Review | 197,984 | 1,533 |
| Postmarket Assurance | 12,145 | 547 |
| Internal Capacity | 66,646 | 404 |
| External Leverage | 13,088 | 171 |
| Program Total | 289,863 | 2,655 |
| BIOLOGICS | | |
| Prescription Drug User Fee Act | 64,608 | 493 |
| Blood and Blood Components | 35,587 | 424 |
| Biologics Compliance | 24,233 | 159 |
| Program Total | 124,428 | 1,076 |
| ANIMAL DRUGS AND FEEDS | | |
| New Animal Drug Review | 18,906 | 186 |
| Postmarket Assurance | 26,068 | 257 |
| Program Total | 44,974 | 443 |
| MEDICAL DEVICES AND RADIOLOGICAL HEALTH | | |
| Premarket Review | 55,035 | 620 |
| Science, Technology and Standards | 10,890 | 121 |
| Postmarket Assurance | 14,590 | 163 |
| Compliance | 38,152 | 416 |
| Mammography Quality Standards Act | 24,580 | 111 |
| Radiation Control for Health and Safety Act | 12,707 | 139 |
| Program Total | 155,955 | 1,569 |

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

| | | |
|---|---------------|------------|
| Build Knowledge Bases | 4,593 | 15 |
| Develop New Strategies for the Prediction of Toxicities | 10,222 | 82 |
| Methods-, Agent-, Concept-Driven Research | 16,764 | 128 |
| Program Total | 31,579 | 225 |

TOBACCO

| | | |
|----------------------|----------------|-----------|
| Tobacco | 134,000 | 50 |
| Program Total | 134,000 | 50 |

Resource amounts are based on FY 1999 Request and include resources for Budget Authority and User Fees (i.e., PDUFA, MQSA and Exports).

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FOODS

PROGRAM RESOURCES (FY 1999)

| Cluster | \$000 | FTEs |
|-----------------------------------|------------------|----------------|
| 1. FOOD AND COLOR ADDITIVE REVIEW | 18,380 | 200 |
| 2. FOOD SAFETY ASSURANCE | 166,078 | 1,623 |
| <i>FSI</i> | <i>[110,591]</i> | <i>964</i> |
| 3. INTERNAL CAPACITY BUILDING | 37,420 | 342 |
| <i>FSI</i> | <i>[27,344]</i> | <i>[156]</i> |
| 4. COORDINATION | 26,839 | 278 |
| <i>FSI</i> | <i>[15,787]</i> | <i>[138]</i> |
| PROGRAM TOTAL | 248,717 | 2,443 |
| <i>FSI</i> | <i>[153,722]</i> | <i>[1,258]</i> |

Note: Clusters 2, 3, and 4 include FSI and non-FSI activities. Base resources allocated specifically to FSI in FY 1997 and incremental resources allocated to FSI in FY 1998 and FY 1999 appear in brackets.

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***STRATEGIC FUTURE
(FY 1999-2004)***

FDA's activities to ensure the safety of food products are important to every consumer. This is largely because these products, which are used daily, are susceptible to contamination by a wide variety of substances including microbial pathogens, chemicals and illegal food additives, which can have a serious adverse impact on human health. Recent estimates on infectious diseases indicate that foodborne contaminants, particularly microbial pathogens, are significant contributors to illnesses and deaths that occur annually in the U.S. Major food safety issues currently confronting FDA include emerging pathogens, new and novel food ingredients, hazardous dietary supplements, naturally occurring foodborne toxins, and international trade. In addition, concerns for safety and nutrient quality are raised by some of the new processing systems and the rapidly expanding array of ready-to-eat convenience foods that require little or no further cooking or preparation prior to eating.

In order to deal effectively with these and other major food safety issues, FDA has decided to focus on two major goals over the next five years. Specifically, these are to complete efforts to reform the premarket approval process for food and color additives and to implement the Presidential Food Safety Initiatives, which incorporate innovative strategies for significantly improving the safety of the nation's food supply.

Efforts to reform the premarket approval process for food and color additives began several years ago, and a number of efforts to streamline the petition review process have already been initiated. Additional reforms are required to further reduce the petition inventory and ensure that a streamlined process is established that assures the timely completion of petition reviews. Also, the new FDA Reform legislation requires that FDA implement a notification procedure for indirect food additives in FY 1999.

In May 1997, the President announced a multi-agency Presidential Food Safety Initiative (FSI), in which Federal and state agencies were asked to work together to develop a comprehensive plan to enhance the safety of the nation's food supply. The primary objective of the FSI is to reduce foodborne illness. It is estimated that, when totally implemented by all participating organizations, the FSI could ultimately "prevent 2 to 9 million illnesses, head-off up to 3,000 deaths and save society billions of dollars in preventable health care costs each year."

On October 2, 1997, the President expanded the FSI to include an initiative directed at developing a more coordinated and effective multi-agency effort on improving the safety of fresh fruits and

vegetables. This initiative responds to the rapidly increasing number of illness outbreaks in recent years that have been attributed to microbial contamination (e.g. Cyclospora, Hepatitis A, and E. coli 0157: H7) in domestic and imported and minimally processed fresh produce. This Initiative directs FDA and other Federal agencies, including the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), Centers for Disease Control and Prevention (CDC), and Department of Labor (DoL), to develop guidance and work with domestic and foreign growers, processors and manufacturers to prevent hazardous contamination of fresh produce.

FDA's participation in the development of the Food Safety and Fresh Produce Initiatives provides two important opportunities for enhancing its food safety activities. First, these initiatives re-emphasize FDA's commitment to using preventive quality control systems and to working with other Federal agencies to expand the use of these systems throughout the food industry. Second, they allow the Agency to significantly improve the efficiency and effectiveness of its regulatory programs by working cooperatively and collaboratively with other Federal agencies, states, professional associations, academia and industry.

In addition, the FSI will permit FDA to continue efforts to work with other Federal agencies to develop more comprehensive and accurate baseline data on foodborne illnesses in the U.S. This effort began in FY 1995, when FDA and USDA worked with CDC and funded the establishment of a pilot (Sentinel Site) project. The Sentinel Sites are an active surveillance program that will provide better baseline data on foodborne illness in this country. Since the initial pilot, Sentinel Sites have expanded to provide greater coverage of representative areas in the nation. With the FY 1998 FSI funds, Sentinel Sites will be operating in areas that are representative of the geographic and demographic distribution in the U.S. By the year 2002, these Sites will be able to produce the volume and quality of baseline data against which we can more accurately measure decline in foodborne illnesses. Moreover, these data will be critical to efforts by FDA and other Federal agencies to establish more realistic and measurable performance goals and targets for their food safety programs.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

| |
|--|
| FY 1999 Performance Goal Highlights |
|--|

Cluster: Food and Color Additive Review \$18,380,000 FTEs: 200

Cluster Rationale: Under the Food, Drug, and Cosmetic Act (FD&C Act), food and color additives must receive premarket approval before entering commerce. To receive approval, sponsors must submit a petition containing appropriate test data to demonstrate the safety of the intended use of the additive. Upon completing the review, the Agency publishes its decision regarding the petition in the Federal Register.

1. Review 30% of food and color additive petitions within 360 days.
2. Reduce the number of overdue food and color additive petitions to 30% of those petitions under review.
3. Finalize rulemaking creating a premarket notification process for independent GRAS determinations.

This performance goal cluster includes all premarket review and consultation activities within the Foods Program that are associated with food additives, color additives, Generally Recognized As Safe (GRAS) food ingredients, and foods derived from new varieties of crop plants using biotechnology. This is a natural cluster because all of these premarket activities must address the question of whether a petitioned (or notified) food ingredient (direct or indirect) or color additive is safe.

The goals within this cluster focus on streamlining the review process through the allocation of resources to petitions in proportion to the potential risk of the substance to the public health. This results in the most timely review of all submissions while maintaining the integrity and credibility of the review process. Laboratory research programs support premarket review efforts by providing the necessary input to develop science-based standards for use in the premarket review process. These and other reinvention initiatives are consistent with the principles and intent of the new Food and Drug Administration Modernization Act of 1997.

Outcomes from realizing these performance goals include the availability of more high-quality, safe food products from which consumers can choose, and the reduction in development time and costs for the regulated industry.

Resources, Approaches, Processes, Skills, And Technology:

Resources are primarily devoted to petition review, but also include other activities supporting the review process. Food and color additive and GRAS petitions are submitted to FDA by industry, and the data in these petitions must be evaluated to determine if the data supports the safety of the proposed use of the substance. After completing the review, the Agency must either publish a regulation in the Federal Register permitting the proposed use of the additive or publish a

notice denying the petition and specifying the grounds for denial or withdrawal. Intermediate steps include communication with the industry sponsor regarding deficiencies that may prevent the petition from being approved if not corrected.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

FY 1999 Performance Goal Highlights

1. Assure that 50% of the seafood industry is operating under appropriate HACCP systems.
2. Increase the percentage of domestic produce produced using GAP and GMP guidance for minimizing microbial contamination.
3. Begin implementing HACCP regulation in the juice industry.
4. Increase the proportion of adults who use food labels to make nutritious food selections to at least 77%.
5. Work with CDC and other Federal agencies to develop improved baseline surveillance data on foodborne illnesses.
6. Release information on Special Nutritionals Adverse Events to the public more frequently.
7. Achieve adoption of the Food Code by 25% of the states.
8. Assure that the domestic food manufacturing establishments inspected by FDA achieve a 90% rate of conformance with FDA requirements.

Cluster: Food Safety Assurance

\$166,078,000 FTEs: 1,623

Cluster Rationale: The primary goal of the Food Safety Assurance cluster is to provide consumers the greatest assurance possible that food products in the marketplace are safe and in full compliance with laws and regulations governing food processing, distribution and

storage, and proper labeling. This is the largest and most varied aggregation of activities within the Foods Program. This cluster includes food safety activities related to the President's Food Safety Initiatives (FSI) and non-FSI food safety activities. In view of the wide variety of potentially hazardous substances which may contaminate these products, this is a major responsibility which has important implications for the health and well-being of consumers, as well as for the Nation.

The goals of this cluster are accomplished through a variety of mechanisms including food safety compliance monitoring, nutrition and other product labeling activities, and activities related to regulating dietary supplements (including the implementation of the Dietary Supplement Health and Education Act (DSHEA)), infant formulas and medical foods.

Compliance monitoring activities provide coverage for approximately 53,000 domestic establishments involved in the production, storage and distribution of food products and over 2.2 million lots of imported products offered at U.S. ports of entry. These activities cover a wide variety of food-related safety concerns such as microbial pathogens, chemical contaminants, sanitation problems and food defects. Safety and sanitation problems identified through monitoring activities are dealt with through a variety of enforcement activities, such as warning letters, seizures, injunctions, and import detentions as well as industry-initiated product recalls.

Food labeling has become increasingly important in recent years as scientific and epidemiological data have more clearly demonstrated that diets play a critical role in the development of certain human diseases. Scientifically established relationships between diet and disease, including heart disease, cancer, diabetes, and osteoporosis, have significant implications for the health and well-being of consumers. Using information provided on current labeling formats, consumers are better able to make dietary choices that are best suited to their particular nutritional needs and that help maintain their health. This cluster also includes a number of other activities such as those directed at establishing regulations, policies, and standards for dietary supplements and other special nutritional products, such as infant formulas and medical foods. During the past several years, dietary supplements have become a major regulatory concern due to the rapidly expanding use and misuse of products.

An important objective for this cluster in FY 1999 will be to increase efforts in the priority areas identified in the Presidential Food Safety and Fresh Produce Initiatives. Activities which have the most direct impact on this cluster include those related to expanding industry's use of quality control systems, including hazard assessment and critical

control point (HACCP) systems, which prevent food safety hazards; using Federal/state partnerships and state contract inspections to increase the frequency of compliance monitoring in food establishments; developing and implementing guidelines to prevent microbial contamination of fresh fruits and vegetables; and increasing efforts to integrate FDA's inspection activities and share monitoring data with states and other Federal agencies.

Ultimate outcome-oriented goals and performance measures are difficult to establish and track due to the inability to relate specific regulatory initiatives to health quality and disease statistics. This problem is exacerbated by the fact that foodborne illness outbreaks do not follow a linear pattern but tend to vary significantly from year to year depending on a variety of circumstances. Moreover, there are a number of other players in the food safety game, and isolating a particular result to any specific Federal or state agency is problematic. Because of these and other complications and variables, ultimate outcomes are difficult to establish and track even with the most comprehensive databases.

Resources, Approaches, Processes, Skills, and Technology:

HACCP

The resources provided under the Food Safety Initiative in FY 1998 and FY 1999 will permit FDA to promptly verify that domestic seafood establishments have adequate HACCP systems. In addition, FDA will increase effort to work with industry to expand HACCP to fresh juices and other appropriate non-seafood segments of the food industry. A major initiative for FY 1998 and FY 1999 will be preparation for the implementation of the HACCP regulation for the juice industry. The Agency will also continue to develop pilot HACCP programs for other segments of the food industry. Based on the results of the pilot programs, FDA will develop strategies for expanding HACCP to other appropriate food industries.

Guidance (GAPs/GMPs) for the Domestic and Foreign Fresh Produce Industries

The additional resources for the Fresh Produce Initiative will permit FDA to increase efforts to work cooperatively and collaboratively with other Federal agencies, state governments, foreign governments and industry to develop and implement voluntary good agricultural practice and good manufacturing practice (GAP/GMP) guidance for fresh fruits and vegetables. In the U.S., FDA will work with USDA and states in this effort. In foreign countries, FDA expects to engage in similar cooperative arrangements with foreign governments, international organizations (e.g., United Nation's Food and Agricultural Organization (FAO) and World Health Organization (WHO) and exporter associations. In addition, FDA will work through USDA's Foreign

Agriculture Service (FAS) and the State Department to facilitate the development of education programs for foreign producers. By working with and through these other organizations FDA hopes to achieve maximum efficiency and effectiveness in this effort to significantly reduce potentially harmful microbial contamination on fresh produce.

Coverage of the Nation's Food Supply

Several strategies will be used to improve the monitoring of the nation's food supply. One strategy will focus on increasing Federal/state partnerships to help achieve this objective. Another strategy will focus on increasing imports coverage through the expanded use of equivalency, MOU and MRA agreements with foreign governments. Equivalency agreements are possible with other nations when FDA has determined by its own investigations that their food safety systems are at least comparable to those in the U.S. Under MOUs and MRAs, producer nations are responsible for ensuring the safety and sanitation of foods before they are exported to the U.S. In addition, efforts will be made to improve the efficiency of domestic and import monitoring activities through more extensive uses of automated systems for reporting and analyzing inspection results.

Early Warning System

FDA will increase efforts to work with other Federal and state agencies to enhance the monitoring and surveillance of foodborne disease, to upgrade the national surveillance system for foodborne infections, to enhance monitoring under HACCP and to develop better techniques for characterizing foodborne pathogen isolates.

Assumptions:

Seafood HACCP

Effective implementation of the Seafood HACCP regulation is based on following assumptions:

1. The Agency must be able to hire up to 80 investigators/microbiologists to work on the HACCP verification effort.
2. Some HACCP inspections will be conducted under state partnerships and state contracts.

Guidance (GAPs/GMPs) for the Domestic and Foreign Fresh Produce Industries

Many of the goals for this activity are based on the assumption that Congress will appropriate the increases requested in the FY 1999 budget for the Fresh Produce Initiative. Without the additional resources, FDA will not be able to achieve goals that are critical to its efforts to increase the safety of fresh produce.

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STRATEGIC GOAL AREA: INTERNAL CAPACITY

Cluster: Internal Capacity

\$37,420,000

FTEs: 342

Cluster Rationale: The Internal Capacity Building cluster focuses on conducting the scientific research and related activities that are needed to develop and maintain the regulatory program required to address twenty-first century food safety issues effectively. This activity groups both laboratory and non-laboratory research investigations that address questions of immediate applicability to regulatory problems, and fundamental studies that can affect FDA review and regulatory responsibilities over the longer term. As defined within this cluster, research includes the development of new analytical approaches and methodologies,

but excludes routine laboratory or non-laboratory testing and analysis using established methodologies. This cluster includes research related to the President's Food Safety Initiatives (FSI).

One important goal of this cluster is the implementation of innovative strategies in the Presidential Food Safety and Fresh Produce Initiatives that are designed to facilitate the development and maintenance of a state-of-the-art food science capability. Risk assessment and research strategies contained in the Presidential Initiatives emphasize the development of collaborative research programs with academia, industry and other Federal agencies. This approach is needed because no single segment of the food industry, in the broadest terms (i.e., industry, government, academia, other representatives of the food safety, nutrition, and public health communities), can conduct the research needed to generate the knowledge bases and develop the expertise to ensure the continued safety and wholesomeness of the food supply.

Collaborative Research Initiatives

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) is a key component of FDA efforts to achieve objectives established in the Presidential Food Safety and Fresh Produce Initiatives. JIFSAN's collaborative research program will be conducted under the direction of a cooperative agreement between the University of Maryland at College Park (UMCP) and the FDA. This institute is patterned after the

FY 1999 Performance Goal Highlights

1. Implement a multi-year research plan to develop scientific methods for detecting, controlling and preventing microbial contamination on fresh produce.
2. Develop and improve risk assessment techniques for microbial pathogens.
3. Develop new alternatives to thermal processing systems for processed fresh produce.
4. Conduct studies of factors that cause foodborne pathogens to develop multiple antibiotic resistance and resistance to traditional food preservation techniques.

National Center for Food Safety and Technology (Moffett Center) in Chicago, Illinois. These programs bring together the resources of industry, academia and FDA to address food safety issues.

The activities of this cluster will benefit consumers by permitting FDA to ensure a safer food supply and, thereby, help reduce the impact of food-related illnesses. This will be accomplished primarily by developing and maintaining the capability to respond more rapidly to health emergencies; taking regulatory actions based on the latest scientific information; and targeting compliance monitoring and research resources where the greatest needs exist. Another important benefit of the enhanced collaboration with other agencies will be more comprehensive and coordinated regulatory activities without significant additional costs.

Resources, Approaches, Processes, Skills, and Technology: The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) was established between FDA and the University of Maryland College Park (UMCP) in April 1996 to create a partnership that will allow for more efficient use of research resources and enhance the quality of food safety and nutrition research and public health policy. As the role of FDA research scientists in regulatory activities increases, it is vital that these scientists have ready access to the very specialized research facilities and expertise (e.g., Center of Bimolecular Structure and Organization) in close proximity to FDA administrative offices to expedite regulatory policy and decisions (e.g., petition review). The resources provided for the Food Safety Initiative and Fresh Produce Initiative in the FY 1999 budget will permit FDA to expand research efforts in JIFSAN and the Moffett Center that are required to fill critical gaps in its food science capability. This includes more rapid and accurate analytical methods for bacterial agents in foods, especially those that are difficult to detect (e.g., Cyclospora) as well as techniques to more effectively prevent and control microbial pathogens on foods. There will also be an expansion of research efforts to improve risk assessments and risk management techniques, particularly for microbial contamination on fresh produce. The results of this research will enhance FDA's ability to more rapidly and accurately characterize the nature and size of the risk to human health associated with foodborne hazards, and make clear the degree of scientific certainty of the data and the assumptions used to develop safety estimates. More rapid and accurate risk assessment techniques are critical to Agency efforts to provide consumers greater protection against potential hazards posed by foodborne pathogens. Other resources to support research in these areas will be obtained through public-private research partnerships using the cooperative research and development agreement (CRADA) process.

These and other expanded research efforts made possible through fully funded Food Safety and Fresh Produce Initiatives will significantly increase the capability of FDA's scientists to provide technical guidance and assistance to industry, consumers, and other constituencies on improving the safety of foods. In addition, these scientists will be better equipped to serve as national and international experts who provide technical expertise for the development and harmonization of international food safety specifications and standards.

Assumptions: The goals established under this cluster assume the following:

1. Requested amounts will be appropriated for the FSI and Fresh Produce Initiative.
2. Funding for Cooperative Agreement with UMCP will continue.
3. Post-doctoral and graduate students will be available through UMCP.

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STRATEGIC GOAL AREA: EXTERNAL LEVERAGING

FY 1999 Performance Goal Highlights

1. Reduce the prevalence of reported risky food consumption behavior and risky food preparation/handling practices, and increase the use of thermometers during cooking.
2. Participate in international organizations that set food safety standards.

Cluster: Coordination

\$26,839,000 FTEs: 278

Cluster Rationale: The Coordination cluster includes goals related to the Cooperative Programs, the Presidential Food Safety Initiatives, international harmonization and standards setting activities, consumer and industry education activities, and coordinated regulatory initiatives with other Federal and state agencies. Consumer and industry education and enhanced coordination between Federal and state agencies on food safety are key components of the Food Safety Initiative. Performance goals within the cluster permit FDA to use external relationships and education/technical assistance activities to expand the impact of its regulatory programs, provide information that can help prevent contamination and reduce the chances of foodborne illness, and leverage the resources of other organizations to enhance

the safety of food. Moreover, many of the activities within this cluster are cross-cutting and, therefore, provide support critical to achieving the regulatory objectives of the other clusters, especially Food and Color Additive Review and Food Safety Assurance.

Cooperative programs with states and Federal agencies, which constitute a major component of this cluster, permit FDA to expand coverage of the food supply significantly. These activities include Memoranda of Understanding (MOUs) with states and Federal agencies on the regulation of milk products, shellfish and retail food operations. Through these cooperative activities with states, the Agency is able to assure that safety and sanitation standards applied to milk, shellfish and retail food operations are adequate and uniform across the Nation. Education and technical assistance activities, another key component of this cluster, permit FDA to develop and implement cost-effective strategies for providing information to consumers and industry that will help to reduce the risk of illness from foodborne infections. These activities are crucial to accomplish the goals of the FSI and Fresh Produce Initiatives. Under the FSI, the Agency will continue efforts to design and implement innovative methods to more effectively deliver food safety messages to consumers and retail food operations (especially institutional food service operations such as hospitals, nursing homes and day care centers), where large percentages of food-related infections occur.

Under the Fresh Produce Initiative, FDA will work to ensure that training and technical assistance is provided to foreign and domestic growers, processors and manufacturers of fresh fruits and vegetables to ensure adoption of safety principles contained in GAPs. This effort will be undertaken jointly with other organizations, including Federal agencies, state governments, foreign governments, international organizations and the foreign and domestic industries. In this country, FDA will work primarily with USDA and states to provide training and technical assistance on GAPs and other safety guidance. In exporting countries, FDA expects to develop cooperative arrangements with foreign governments, international organizations (e.g., FAO/WHO), and exporter associations to ensure the adoption of the voluntary safety guidance. Moreover, FDA will work through FAS and the State Department to facilitate the development of education programs for foreign producers. Through these joint efforts, FDA will achieve maximum efficiency and effectiveness in this effort to significantly increase the safety of fresh produce.

Full participation in efforts of international standard setting organizations including those dealing with the General Agreement on Tariffs and Trade (GATT), the North America Free Trade Agreement (NAFTA), and Codex Alimentarius, is required if FDA is to promote the

development and adoption of science-based international safety standards and control systems for foods. Acceptance and utilization of international standards that satisfy U.S. consumer protection goals will improve product safety and public health, reduce FDA's import inspection burden, and facilitate the import and export of foods. Data are currently not adequate to establish baselines for many of the activities that support the goals of this cluster as well as the other clusters in the Foods Program. In FY 1999, FDA will continue its efforts to improve the amount and quality of data needed to more thoroughly assess the impact of its efforts to assure the safety of the nation's food supply and establish appropriate intermediate outcome measures for some of these activities. One effort will attempt to supplement information from FY 1998 consumer research activities with information from the Behavioral Risk Factors Survey (BRFS) and Food Safety Surveys to track the effectiveness of educational campaigns and programs. Efforts to measure the impact of the Public Affairs Specialist (PAS) activities related to foods using informal surveys and PAS feedback on services and needs will continue. In addition, FDA will work with USDA to conduct surveys required to obtain data to evaluate the effectiveness of, and the extent to which the fresh produce industry has adopted guidance for improving the safety of fresh produce.

Resources, Approaches, Processes, Skills, and Technology: With resources in FY 1999, FDA will expand effort to significantly reduce the potential for foodborne illnesses through new and innovative education and information sharing programs; more effective coordination with Federal agencies and states on foodborne disease surveillance as well as responses to foodborne illness outbreaks; and efforts to harmonize international standards for food safety and sanitation. These represent some of the most cost-effective strategies available for preventing foodborne infections.

FDA will expand efforts to work with Federal and state agencies to develop and implement innovative food safety education programs to reduce the potential for foodborne illness by changing unsafe food handling behaviors in the home and in retail food establishments. In one of the major efforts to be undertaken in this area, FDA and its partners will use concepts set forth in the Food Code to develop and implement a national education program directed at improving food handling practices of consumers and the retail food industry. The Food Code is designed to help state and local regulatory agencies develop or update their own food safety rules and to assure consistency between jurisdictions on the regulation of grocery stores, restaurants, and institutions that sell or serve food across the United States.

FDA will increase its efforts to play a major leadership role in influencing worldwide food safety standards so that it can ensure a safer food supply for U.S. consumers. This will mean that FDA will actively participate in a wide variety of international organizations that address food safety issues. Those who represent the Agency in these organizations must thoroughly understand Federal food regulations and standards and the science that supports them. As indicated in the Internal Capacity cluster, FDA scientists must be well equipped with knowledge and experience to provide expert scientific advice on safety standards. Such knowledge and expertise is critical to evaluate proposals for international safety standards and control systems that assure comparability with the nation's domestic standards. In addition, FDA will increase its efforts to work with other Federal agencies to develop and implement an "early warning" system that will ensure more coordinated and rapid responses to foodborne illness outbreaks. This will include working with other Federal and state agencies to enhance the monitoring and surveillance of foodborne disease, to upgrade the national surveillance system for foodborne infections in humans, and develop better techniques for characterizing foodborne pathogen isolates. Reducing the response time to illness outbreaks is vital to Agency and Departmental efforts to significantly reduce the adverse health and economic impacts of food-related health emergencies.

Assumptions: The goals for this cluster are based on the assumptions that:

1. The requested increases for the FSI and Fresh Produce Initiative will be fully funded.
2. Resources for activities not covered under the two Presidential Initiatives will be at or near the current level.

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FOODS PERFORMANCE GOALS

Strategic Goal **PREMARKET REVIEW**

Area:

Cluster: **Food and Color Additive Review**

1. *By the end of FY 1999, complete reviews of 30% of food and color additive petitions within 360 days.*

Agency
Strategies: Streamline reviews.

Data Sources: An electronic document management and workflow system is being developed to facilitate tracking and assignment of petition reviews.

Baseline Data: Under development. FDA does not have quantitative baseline data

comparable to this goal (See note).

FY 1997: The information technology infrastructure required to support this system has been upgraded; and a prototype document management and workflow system has been designed and was tested.

FY 1998: Document management and workflow system is being tested.

Note about Baseline Data: In the past, actions included issuance of a "reject" letter based on partial reviews of petitions. FDA is now committed to timely review of a complete petition package within time frames in performance goals. Previously, performance measures were reported for the year in which an action was taken on a petition rather than the year in which the petition was filed with the FDA (the reference which will be used to measure this goal). This and other changes in the FDA review process, including those required by the FDA Modernization Act, are expected to change the spectrum of submissions received by the FDA.

2. *By the end of FY 1999, reduce the number of overdue food and color additive petitions to 30% of those petitions under review.*

Agency Strategies: Streamline reviews.

Data Sources: An internal tracking database will be improved and incorporated in the electronic workflow system mentioned in Goal #1 above.

Baseline Data: FY 1997: As of the end of FY 97, 44% of petition under active review were "overdue" (defined as under review for more than 180 days, the statutory time frame).

3. *During FY 1999, finalize the rulemaking creating a premarket notification process for independent generally recognized as safe (GRAS) determinations.*

Agency Strategies: Focus on high priority applications.

Data Sources: Finalized rulemaking will be published in the *Federal Register*.

Baseline Data: Currently, the review of FDA's GRAS affirmation petitions is time-consuming and resource-intensive. The proposed rule will replace the existing process used by sponsors to notify FDA of their independent GRAS determinations and, in response to the reinvention government initiative (REGO), will streamline and expedite the review process.

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Strategic Goal Area: POSTMARKET ASSURANCE

Cluster: Food Safety Assurance

1. *By 12/30/99, 50% of the seafood industry will be operating preventive controls for safety as evidenced by functioning, appropriate HACCP systems [1].*

Agency Strategies: Develop science-based products and process standards and guidance;
Agency Strategies: Inform and assist firms to achieve conformance; Foster industry quality

assurance programs, e.g., HACCP; Maintain inspection visibility.

Data Sources: FDA's Field Data System; National Seafood HACCP Compliance Database System.

Baseline Data: FY 1996: FY 1996 compliance data based on establishment inspections indicate that a minority of establishments in the seafood industry will operate under the Seafood HACCP regulation as published.

FY 1997: indicate that a minority of establishments in the seafood industry will operate under the Seafood HACCP regulation as published.

FY 1998: Conduct verification inspections of the domestic seafood industry to ensure that adequate seafood HACCP systems are in place. Provide technical assistance as required to help firms correct deficiencies.

FY 1999: Complete verification inspections of the Seafood industry to ensure that HACCP has been adequately implemented.

2. Increase the percentage of domestic produce produced consistent with voluntary good agricultural practices (GAP)/good manufacturing practices (GMP) broadscope guidance to reduce microbial contamination [1].

Agency Strategies: Inform and assist firms to achieve compliance; Maintain inspection visibility; Develop science-based products and process standards and guidance.

Data Sources: FDA's Field Data System; USDA's 1998 and 2000 National Agricultural Statistics Survey (NASS) Vegetable Chemical Use Surveys, 1997, 1999 and 2001 NASS Fruit Chemical Use Surveys; USDA compliance data systems.

Baseline Data: FY 1998: Conduct grassroots meeting on good agricultural practices (GAPs) and good manufacturing practices (GMPs) guidance with domestic and foreign fresh produce growers, producers, processors and manufacturers. Issue broadscope guidance on GAPs/GMPs for growers and producers of fruit and processors of fresh produce in July 1998. USDA conducts 1998 NASS Vegetable Chemical Use Survey. Obtain baseline data from USDA's compliance data systems and USDA's 1997 NASS Fruit Chemical Use Survey. Obtain baseline data from USDA's 1998 NASS Vegetable Chemical Use Survey and USDA compliance data systems.

FY 1999: USDA conducts 1999 NASS Fruit Chemical Use Survey. Obtain data from USDA's 1999 NASS Fruit Chemical Use Survey and USDA compliance data systems.

FY 2000: USDA conducts 2000 NASS Vegetable Chemical Use Survey.

FY 2001: USDA conducts 2001 NASS Fruit Chemical Use Survey. Compare baselines with USDA's 2000 NASS Vegetable Chemical Use Survey and 2001 NASS Fruit Chemical Use Survey to evaluate the adoption and compliance with the voluntary GAPs and GMPs guidance.

3. *During FY 1999, take steps to implement the HACCP regulation for the juice industry, including providing training, technical assistance and guidance to industry and states [1].*

Agency Develop science-based product and process standards and guidance;
Strategies: Foster industry quality assurance programs, e.g., HACCP; Collaborate with Federal and state regulators to reduce health risks.

Data Sources: FDA Field data systems.

Baseline Data: FY 1997: 1997 E. coli O157:H7 contamination in apple juice resulted in one death and 66 illnesses (including 14 with hemolytic uremic syndrome).
FY 1998: At present, there are no established juice HACCP regulations or guidelines.

4. *By the end of FY 1999, increase to at least 77% the proportion of people aged 18 and over who use food labels to make nutritious food selections.*

Agency Inform and assist firms to achieve compliance; Empower consumer
Strategies: choice through product labeling and education.

Data Sources: Tracked by FDA's Diet and Health Survey.

Baseline Data: FY 1995: 74%
FY 1996: 75%

5. *During FY 1999, work with the Centers for Disease Control and Prevention (CDC) and other Federal agencies to develop baseline surveillance data on foodborne illnesses required to evaluate the effectiveness of, set better priorities for, and determine appropriate outcomes for the Food Safety Initiative [1].*

Agency Improve surveillance and follow-up on adverse events.
Strategies:

Data Sources: FoodNet Sentinel Site surveillance system. CDC, state and local health department passive surveillance systems.

Baseline Data: FY 1995: FDA and USDA worked with CDC and funded the establishment of a pilot (Sentinel Site) project. This is an active surveillance program that will provide baseline data on foodborne illness in the U.S.
FY 1996 & 1997: Sentinel Sites expanded to provide better coverage of the representative areas of the U.S.
FY 1998: Using FSI funds, eight Sentinel Sites will be operating in areas that are representative of the geographic and demographic distribution in the U.S.
FY 2002: Sentinel Sites will be able to produce baseline data against which change in foodborne illnesses can be measured.

6. *By the end of FY 1999, improve public access to timely information on adverse events related to dietary supplement products, infant formulas, and medical foods by increasing*

the frequency of public releases of information in the Special Nutritional Adverse Events Monitoring System (SN/AEMS) from 2 per year to 4 per year.

Agency Improve surveillance and follow-up on adverse events. Empower
Strategies: consumer choice through product labeling and education.

Data Sources: Special Nutritional Adverse Events Monitoring System (SN/AEMS).

Baseline Data: FY
1997: two releases.

7. *By the end of FY 1999, enhance the safety of the nation's food supply by achieving adoption of the Food Code by 25% of the states [1].*

Agency Inform and assist firms to achieve compliance.
Strategies:

Data Sources: FDA's Field Data System.

Baseline Data: FY
1997: Three states have adopted the Food Code: Utah, Rhode Island and Mississippi.

8. *Assure that FDA inspections of domestic food manufacturing establishments, in conjunction with the timely correction of serious deficiencies identified in these inspections, result in a high rate of conformance (at least 90%) with FDA requirements by the end of the fiscal year.*

Agency Inform and assist firms to achieve compliance.
Strategies:

Data Sources: Field Data Systems.

Baseline Data: FY
1996: 98% (see note)

Note about Baseline Data: Prior compliance performance measures have been essentially counts of activities at various points along the enforcement continuum*i.e.*, number of inspections, violative inspections, warning letters, prosecutions, etc. This new measure strives to integrate the results of these activities into an end-of-the-year statement about the compliance status of this specific industry sector. A prototype of the new measure will be generated in FY 1998.

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Strategic Goal **INTERNAL CAPACITY BUILDING**
Area:

Cluster: **Internal Capacity**

1. *Implement a multi-year research plan to develop and improve methods for the detection, control and prevention of microbial contamination on fresh produce and evaluate the effectiveness of technologies for eliminating this contamination [1].*

Agency Develop science-based product and process standards and guidance;
Strategies: Consolidate and prioritize research activities; Collaborate with Federal and state regulators to reduce health risks; Pursue public private partnerships to expand resources.

Data Sources: Progress will be monitored by technology transfers, CRADAs, reduced

costs, etc. and periodic management and peer review.

- Baseline Data:** FY 1997: The limited number of scientific methods are either not effective for fruit and vegetables because the natural constituents of these products frequently interfere with the methods or the method must be modified for the specific commodity.
- FY 1998: Establish an interagency research committee to determine research needs and to plan and coordinate food safety research for FY 1998. Develop long-range research plan that has four major areas of focus (i.e., improved detection methods, antibiotic resistance, resistance to traditional preservation technologies, and intervention strategies).

2. *During FY 1999, develop modeling techniques for assessing human exposure to a variety of foodborne pathogens and for describing low dose infectivity rates for infectious and toxicoinfectious microorganisms [1].*

Agency: Develop science-based product and process standards and guidance;

Strategies: Collaborate with Federal and state regulators to reduce health risks.

Data Sources: Progress will be monitored by periodic management and peer reviews.

Baseline Data: There are no generally agreed upon modeling techniques to assess human exposure to foodborne pathogens and the potential risk of these causing human illness.

3. *During FY 1999, work with industry and academia to develop new techniques for eliminating pathogens on fresh produce where traditional thermal processing systems used for processed foods cause fresh produce to deteriorate and become inedible [1].*

Agency: Develop science-based product and process standards and guidance;

Strategies: Collaborate with Federal and state regulators to reduce health risks.

Data Sources: Progress will be monitored by periodic management and peer reviews.

Baseline Data: Traditional thermal processing systems used for processed foods cause fresh produce to deteriorate and become inedible.

4. *During FY 1999, conduct studies on factors that cause foodborne pathogens to develop multiple antibiotic resistance and resistance to traditional food preservation techniques and factors that prevent the development of such resistance [1].*

Agency: Develop science-based product and process standards and guidance;

Strategies: Collaborate with Federal and state regulators to reduce health risks review standards.

Data Sources: Progress will be monitored by periodic management and peer reviews.

Baseline Data: These phenomena are recent developments and very little research has been conducted to date. The FY 1999 studies will help fill this gap.

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Strategic Goal Area: EXTERNAL LEVERAGING
Cluster: Coordination

1. *Use educational campaigns and activities to reduce the prevalence of reported risky food consumption behavior, reduce the prevalence of reported risky food preparation/handling practices, and increase the percentage of people who report using thermometers to assure the safety of foods during cooking [1].*

Agency Empower consumer choice through product labeling and education;

Strategies: Inform and assist firms to achieve compliance.

Data Sources: FDA's FY 1993, 1998, and 2000 Consumer Survey; and FDA's January 1998 Retail Food Establishment Survey.

Baseline Data: FY 1993: FDA conducted a national survey of the public's knowledge, attitudes and practices related to food safety.
Risky food consumption: Among consumers 18 years or older, 57% reported consuming raw eggs and 25% reported eating undercooked hamburger.
Risky food preparation/ handling: 54% reported leaving raw meat at room temperature for more than 2 hours. 33% did not always wash knives or cutting boards with soap after using them to prepare raw meat and before continuing to prepare a meat. 4% used thermometers to check cooking temperatures.

FY 1997: Develop data collection instrument for FDA's FY 1998 Consumer Survey.

FY 1998: Continue developing data collection instrument for FDA's FY 1998 Consumer Survey; Collect data for FDA's FY 1998 Consumer Survey; Develop and launch educational campaigns and activities on risky food consumption behavior targeting special populations for key safety messages, promoting the use of the Food Code and science-based safety standards, and overcoming barriers to communicating proper food safety behaviors to food service workers.

FY 1999: Continue educational campaigns and activities.

FY 2000: Continue educational campaigns and activities.

2. *During FY 1999, increase the safety of imported foods through participation in international standard setting organizations (such as Codex Alimentarius of the United Nations World Health Organization (WHO) and the Food and Agricultural Organization (FAO), the North American Free Trade Agreement's (NAFTA) Standard Phytosanitary Committee, and the World Trade Organization (WTO)) that consider or establish international standards for food safety and sanitation [1].*

Agency Support U.S. interests in global standard setting; Increase coordination

Strategies: of international harmonization activities.

Data Sources: Food safety and sanitation standards of standard setting organizations.

Baseline Data: FY 1998: Participate in: all meetings of Codex Alimentarius Committees that elaborate food safety standards including limits for contaminants in foods, codes of practice (e.g.,

GMPs) and guidelines (e.g., HACCP and decisions on equivalence); all WTO and NAFTA SPS matters involving food safety; discussion of all trade disputes involving legal interpretation of provisions of trade agreements that have implications in upholding U.S. food safety requirements.

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1. Achievement of goal assumes that additional personnel can be acquired via contract or other means.

HUMAN DRUGS

PROGRAM RESOURCES (FY 1999)

| Cluster | \$000 | FTEs |
|-------------------------|----------------|--------------|
| 1. PREMARKET REVIEW | 197,984 | 1,533 |
| 2. POSTMARKET ASSURANCE | 12,145 | 547 |
| 3. INTERNAL CAPACITY | 66,646 | 404 |
| 4. EXTERNAL LEVERAGE | 13,088 | 171 |
| PROGRAM TOTAL | 289,863 | 2,655 |

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STRATEGIC FUTURE (FY 1999-2004)

The Human Drugs Program assures that all drug products for the prevention, diagnosis, and treatment of disease are safe, effective and properly labeled. Premarket review, supporting research, education, and information technology will remain the critical program elements necessary to assure drug safety and efficacy.

In the premarket arena, the Human Drugs Program will continue to pursue strategies that streamline the drug review process, reduce approval time for new product approvals, focus on high priority applications, cope with ever-increasing workload, support timely sponsor decision-making regarding optimal drug development, and generally enhance the efficiency of U.S.-based biomedical research efforts. The broader expectation for this effort over the five-year term of the renewed user fee authority is a more timely drug development process. The pharmaceutical industry has expressed hopes that they can save up to one year of the current product development timetable

if FDA can support them with timely assistance and advice during the development process. This is a new, and quite challenging expectation for the next five years.

For postmarket activities, the Program will continue to inform and assist firms in complying with the law and regulations, and to communicate product and process standards effectively. Compliance programs will target those domestic and imported products which represent the greatest public health risk.

State-of-the-art information systems will continue to play a key role in reducing the time required to bring new products to market. Improved review processes will enhance internal and external communication, decrease the cost and time to file applications and reports, and increase the availability of information to consumers.

A central characteristic of the Human Drugs Program for the future is the ability to leverage limited Agency resources by working with key outside stakeholders including the regulated industry, fellow regulators, the international community, and the consumer.

International harmonization will permit FDA to make more efficient use of its resources as other countries share the workload of developing new standards. The Human Drugs Program will also continue to enter into partnerships with states, other Federal regulatory agencies, and universities.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

Cluster: Premarket Review

\$197,984,000 FTEs: 1,533

Cluster Rationale: Under the Food, Drug and Cosmetic Act (FD&C Act), all new drugs must be evaluated for safety and effectiveness and approved prior to marketing. The prompt approval of safe and effective new drugs is vital to improving of the public health.

This cluster groups all the premarket review and approval activities of the Human Drugs Program. Numerous initiatives to improve efficiency and streamline premarket drug review are proposed or have been implemented.

This cluster supports the Agency's premarket review goal area by streamlining reviews, informing and assisting product sponsors, and focusing on high-priority reviews. It includes:

- monitoring pre-clinical and clinical trials to support investigational new drugs;
- evaluating new drug applications and abbreviated new drug applications for marketing of new drugs, new molecular entities and generic drugs;
- developing and maintaining the scientific research necessary to achieve greater efficiency and effectiveness of operations;
- reducing the time required to review drugs for life-threatening diseases such as AIDS, AIDS-related diseases and cancer; and
- conducting pre-approval inspections of drugs to assure compliance with current good manufacturing practices, application commitments and data integrity.

Three immediate outcomes from realizing these performance goals are availability of critically needed medical therapies, greater variety of choices for consumers, and lower cost and higher economic benefits. The ultimate outcome is to contribute to longer and healthier lives of the American people.

FY 1999 Performance Goal Highlights

1. Review and act on 90% of standard new drug applications (NAS) filed within 12 months after receipt (30 percent within 10 months of receipt) and priority applications within 6 months.
2. Review and act on 90% of complete NDA applications resubmitted following receipt of a non-approval letter within 6 months after resubmission date.
3. Review and act on 60% of fileable original generic drug applications within 6 months after submission date.
4. Review and act on 90% of standard efficacy supplements within 12 months (30% within 10 months of receipt) and priority efficacy supplements filed within 6 months of receipt.
5. Review and act on 90% of manufacturing supplements within 6 months and act on 30% of manufacturing supplements requiring prior approval within 4 months

Resources, Approaches, Processes, Skills, and Technology:

Performance over the past five years has proven the ability of user fees to enhance the quality and capacity of the drug review process. Dramatic reductions in approval times have resulted from FDA's ability to review new drug applications within accelerated performance timeframes. In FY 1999 the Agency will be applying this proven performance capability in three directions. First, the review workload of FY 1999 will likely be on the order of 20 percent larger than that experienced in FY 1997. Building this added capacity to meet the expanding workload while responding to more stringent review time frames will be a formidable challenge by itself. Secondly, FDA will be in the midst of a transformation to an electronic submission process. Success in this endeavor will be necessary to meet out-year performance commitments. Thirdly, FDA will be starting to meet the first performance expectations related to accelerating the development process for new drugs.

The second and third of these directions will require substantial degrees of partnership and collaboration with industry. Measurement of an accelerated development cycle presents special challenges since so few of the new product development milestones are visible to FDA. To follow trends in the development process, FDA will rely on statistics collected and published by various private sector organizations specializing in measurement of the drug development process. Industry-supported data systems managed by organizations such as the Center for the Study of Drug Development and the Center for Medicines Research International offer the promise of early signals of improvement in key phases of the overall process. FDA will interact with such organizations in FY 1999 to encourage the measurement of the early signs of a faster pace of development perhaps as early as 2000.

Assumptions: PDUFA has been a successful industry and FDA effort. During 1996, FDA took more actions on product applications and approved more new molecular entities than in any other single year in the Agency's history. That same year, FDA approved 87 percent more new drug applications (NDA) than in 1993. Prospects for continued success is dependent upon the mutual efforts of both industry and FDA. Funding must also be available which will support the multi-year performance goals to which this Agency is now committed.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Postmarket Assurance

\$12,145,000

FTEs: 547

Cluster Rationale: Postmarket surveillance provides additional safety information that cannot realistically be developed prior to drug approval.

This cluster supports the Agency's postmarket assurance goal area by informing and assisting firms to achieve compliance, targeting high priority domestic and import risks, improving surveillance and follow-up on adverse events, maintaining inspectional visibility, and

developing science-based product and process standards.

Immediate outcomes from realizing these performance goals are improved postmarket safety information about marketed drug products; removal of misbranded, unsafe or violative drug products by voluntary actions, recalls, withdrawals, discontinuations or enforcement actions; identification of high-risk domestic and foreign products; and working collaboratively with firms to achieve compliance. The ultimate outcome is to assure the American people that the nation's drug supply is safe.

Resources, Approaches, Processes, Skills, and Technology:

Postmarket surveillance information systems are essential to conducting useful surveillance and generating postmarketing safety information. The postmarket assurance activities include: education, policy and standards-setting, postmarketing reporting systems, drug product sampling, testing and surveillance, surveillance inspections, voluntary compliance, and enforcement actions.

Assumptions: This cluster's performance goals are based on the current workload. While a slight increase in the workload may be absorbed within the goals identified, major increases in workload or significant decreases in resources would significantly impact FDA's ability to meet these goals.

During FY 1999, the Drug Registration and Listing System (DRLS) contract is due for renewal. The basis for the DRLS is the Drug Listing Act of 1972. All domestic firms engaged in the manufacture, preparation, propagation, compounding, or processing of drugs are required to register their establishments and list all commercially marketed drug products. This substantial contract directly impacts FDA's ability to ensure the quality of the nation's drug supply.

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FY 1999 Performance Goal Highlights

1. Assure that the domestic drug manufacturing and repacking establishments inspected by the FDA achieve at least a 90% rate of conformance with FDA requirements.
2. Implement the Adverse Events Reporting System (AERS) for adverse drug event (ADE) reports.

FY 1999 Performance Goal Highlights

1. Continue to achieve capacity for electronic submission and archiving of new drug applications (NAS) and ANDAs and AADAs.

Cluster: Internal Capacity

\$66,646,000 FTEs: 404

Cluster Rationale: To accomplish our statutory mandates, enhance responsiveness to our external and internal customers, and comply with the requirements of the National Performance Review, FDA realigned its functional responsibilities to enhance performance, efficiently achieve its mission and improve organizational flexibility. The outcome of these efforts are elimination of backlogs, shortened review times, improved quality of submissions, improved productivity, and high quality scientific decision-making.

Resources, Approaches, Processes, Skills, and Technology:

PDUFA challenged FDA to reduce the time historically taken to review NDAs. To accomplish continuous improvement in a time of changing environment, we had to find less expensive and more efficient ways to process information.

Assumptions: FDA's ability to accomplish its information technology (IT) vision assumes that adequate funding will be available for the acquisition and maintenance of critical IT skills, services, hardware, and/or software. Re-authorization of PDUFA will allow continuation of efforts to deploy information technology to expedite the review process. It is assumed that the necessary funds will be provided each fiscal year until FY 2002 to implement the target environment and that sufficient funds will be provided during the out-years to cover sustaining engineering.

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STRATEGIC GOAL AREA: EXTERNAL LEVERAGING

Cluster: External Leveraging

\$13,088,000 FTEs: 171

Cluster Rationale: FDA has long recognized the need to develop partnerships with other Federal, state, local and international governments, the pharmaceutical industry and consumers.

FDA and the drug industry have undertaken the effort to provide the American public with useful, comprehensive, and easily readable information about prescription and over-the-counter (OTC) drugs. This effort will increase the quantity and the quality of written information provided to consumers receiving new prescriptions and OTC

products. The Agency has proposed the establishment of a standardized OTC label to increase consumers' ability to recognize important warnings and directions for use and allow them to make informed decisions regarding drug products.

Through contacts with foreign government agencies, we are exploring effective ways to share regulatory information about FDA-inspected manufacturers. One potential avenue involves the increased use of the Compliance Status Information System (COMSTAT) database. COMSTAT is one of the first significant efforts at international exchange of good manufacturing practices (GMP) status information. FDA believes that its limited inspection and surveillance resources can best be leveraged through the development of international agreements that assure the safety of products imported into the United States. These agreements allow the Agency to have greater confidence in the validity of product certifications. Foreign government inspection reports provide added value in terms of public health protection and optimal resource allocation.

Resources, Approaches, Processes, Skills, and Technology: FDA recognized early, the importance of its participation in voluntary standards organizations. The International Conference on Harmonization (ICH), an initiative supported by regulatory and industry officials representing the United States, the European Union and Japan, is working to harmonize the format and content of applications for all new drugs and biotechnology products. FDA is participating fully with other ICH members to address the standardization of three areas of drug development: efficacy (human

FY 1999 Performance Goal Highlights

1. Assure the availability, quality and usefulness of prescription drug information provided to 75% of individuals receiving new prescriptions; and complete two studies to develop comprehensive drug information.
2. Continue to improve the legibility and clarity of OTC drug labels, improve the consumer's ability to understand warnings and usage directions.

clinical trials); safety (pharmacology/toxicology); and quality (manufacturing).

Assumptions: FDA assumes on-going and increasing participation by external partners to support and continue our involvement in present and new initiatives. We will build on and expand efforts to achieve international harmonization by launching work on new harmonization topics in the testing of human drugs and standards for the electronic transfer of regulatory information; accelerating work on harmonizing drug good manufacturing practices; good laboratory practices, good clinical practices standards and inspections; and initiating work towards more harmonization with our NAFTA partners.

In FY 1996, CDER processed nine different types of Certificates to Foreign Governments. These certificates enable the manufacturers to export their products to foreign customers and foreign governments and serve to attest that the drug products are subject to inspection by FDA and are manufactured in compliance with current good manufacturing practices. In FY 1995, CDER issued 1,747 certificates and in FY 1996 the demand for certificates increased by 2,752 for a total issuance of 4,499. This increase is due to expanding world trade, ongoing international harmonization initiatives, international development agreements, and the enactment of the Food and Drug Export Reform Enhancement Act.

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HUMAN DRUGS PERFORMANCE GOALS

Strategic Goal Area: **PREMARKET REVIEW**

Cluster: **Premarket Review**

1. *Review and act on 90% of standard new drug applications (NDAs) filed within 12 months after receipt (30% within 10 months of receipt); and priority applications within six months.*

Agency Strategies: Streamline reviews.

Data Sources: Center-wide Oracle Management Information System (COMIS); New Drug Evaluation (NDE)MIS.

Baseline Data: *Standard applications:*

FY 1994: 55%

FY 1995: 70%

FY 1996: 80%

FY 1997: 90%

Priority applications:

Under development. FY 1997 data showing percent reviewed within six month period will be available mid-

FY 1998.

2. *Review and act on 90% of complete NDA applications resubmitted following receipt of a non-approval letter, within six months after resubmission date.*

Agency Strategies: Streamline reviews.

Data Sources: COMIS; NDE/MIS.

Baseline Data: FY 1995: 97%
FY 1996: 99%

3. *Review and act upon 60% of fileable original generic drug applications within six months after submission date.*

Agency Strategies: Inform and assist product sponsors.

Data Sources: COMIS; NDE/MIS.

Baseline Data: FY 1995: 41%
FY 1996: 54%

4. *Review and act upon 90% of standard efficacy supplements within 12 months (30% within 10 months of receipt) and priority efficacy supplements filed within six months of receipt.*

Agency Strategies: Develop science-based process standards.

Data Sources: COMIS; NDE/MIS.

Baseline Data: Not tracked prior to FY 1997.
FY 1997 data not yet available.

5. *Review and act upon 90% of manufacturing supplements within six months and act on 30% of manufacturing supplements requiring prior approval within four months.*

Agency Strategies: Develop science-based process standards; Streamline reviews.

Data Sources: COMIS; NDE/MIS.

Baseline Data: FY 1994: 66%
FY 1995: 90%
FY 1996: 96%

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Strategic Goal Area: POSTMARKET ASSURANCE

Cluster: Postmarket Assurance

1. *Assure the FDA inspections of domestic drug manufacturing and repackaging establishments in conjunction with the timely correction of serious deficiencies identified in these inspections, result in a high rate of conformance (at least 90%) with FDA requirements by the end of the fiscal year.*

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Field data systems.

Baseline Data: Prior compliance performance measures have been essentially counts of activities at various points along the enforcement continuum-i.e., number of inspections, violative inspections, warning letters, prosecutions, etc. This new measure strives to integrate the results of these activities into an end-of-the-year statement about the compliance of this specific industry sector. A prototype of the new measure will be generated in FY 1998.

2. *Implement the Adverse Events Reporting System (AERS) for the electronic receipt and review of voluntary and mandatory ADE reports.*

Agency Improve surveillance and follow-up on adverse events. Implement
Strategies: decision-supportive information systems.

Data Sources: Averse Event Reporting System (AERS).

Baseline Data: Implementing the core system is currently under way and will be completed during FY 1998.

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Strategic Goal
Area: INTERNAL CAPACITY

Cluster: Internal Capacity

1. *Continue to achieve capability and capacity for electronic submission and archiving of information required to submit new drug applications (NDAs), abbreviated new drug applications (ANDAs) and abbreviated antibiotic drug applications (AADAs) without paper copy.*

Agency Streamline reviews; Inform and assist product sponsors. Implement
Strategies: decision-supportive information systems.

Data Sources: Electronic Document Room (EDR).

Baseline Data: By FY 1997, establish the structure of the EDR.
By FY 1998, implement the pilot for accepting and archiving NDAs.

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Strategic Goal
Area: EXTERNAL LEVERAGE

Cluster: External Leverage

1. *FDA will: (a) evaluate the availability, quality and usefulness of prescription drug information provided to 75% of individuals receiving new prescriptions; and (b) complete two studies that will aid in development of comprehensive drug information.*

Agency
Strategies: Consumer empowerment through product labeling.

Data Sources: Keystone Center.

Baseline Data: In 1994, 59% of patients receiving prescription drugs received written information. Assessments are underway to determine the percentage of

this information which met the standards established to define useful. Study topics have been identified and studies are being designed.

2. *FDA will continue to improve the legibility and clarity of OTC drug labels, and improve the consumer's ability to read and understand important warnings and usage directions.*

Agency Consumer empowerment through product labeling. Develop science-based standards.

Data Sources: OTC labeling provisions; Results of studies.

Baseline Data: *Federal Register* publication on February 27, 1997 (62FR9024) published a proposal providing for standardized format for labeling. Study topics have been identified and studies are being designed.

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BIOLOGICS

PROGRAM RESOURCES (FY 1999)

| Cluster | \$000 | FTEs |
|--|----------------|--------------|
| 1. PRESCRIPTION DRUG USER FEES | 64,608 | 493 |
| 2. BLOOD, TISSUES, AND OTHER BIOLOGICAL PRODUCTS | 35,587 | 424 |
| 3. BIOLOGICS COMPLIANCE | 24,233 | 159 |
| PROGRAM TOTAL | 124,428 | 1,076 |

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STRATEGIC FUTURE (FY 1999-2004)

FDA is responsible for assuring that blood and blood products, blood test kits, bacterial vaccines and antigens, viral vaccines, therapeutic agents, and other biological products intended for use in the prevention, diagnosis, and treatment of diseases in humans are pure, potent, safe, and effective, as well as properly labeled for their intended uses.

The Biologics Program includes registration and inspection of blood banks and other firms processing blood; licensing and inspection of firms collecting human source plasma; evaluating and licensing biologics manufacturing firms and products; lot release of licensed

products; removal of ineffective, unsafe, or improperly labeled products from the market; development of necessary regulations, compliance programs and guidelines; and conduct of research, in concert with other HHS public health agencies, academia, and industry, to further development of new products and to provide sound scientific basis for their regulation.

The regulation of biologics has been significantly affected by reinvention initiatives. In 1995, the Agency responded to manufacturers' concerns with a series of measures that included the replacement of 21 application forms with one harmonized version; and allowed the use of small scale pilot facilities during the approval phase of biological products.

Recently, the Agency proposed a truly novel scientific framework for regulating therapies derived from human cells and human tissues. The key feature of this proposal is that the FDA interventions are proportionate to the degrees of risk. Under the proposed regulation, oversight will be commensurate with degree of public health risk. The Agency recently announced two proposed guidances that clarify the quantity and quality of evidence needed to approve a new or supplemental therapeutic indication.

Assumptions:

1. That CBER's PDUFA-related research will be phased out over three years (FY 1998-FY 2000). The reduction in PDUFA research activities will be largely offset by additional PDUFA review activities.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

Cluster: Prescription Drug User Fees \$64,608,000 FTEs: 493

Cluster Rationale: The Food and Drug Administration Modernization Act of 1997 (FDAMA), Public Law 105-115, authorized revenues from fees paid by the pharmaceutical industry to expedite review by the Food and Drug Administration (FDA) of human drug applications. These revenues were directed by section 101(4) of this Act toward accomplishment of goals identified in the letters of November 12, 1997, from the Secretary of Health and Human Services to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate.

Resources, Approaches, Processes, Skills, and

Technology: Resources are primarily devoted to application review, but also include pre-submission meetings and pre-approval inspections.

The FDAMA authorizes the collection of user fees to enhance the review process of new human drug and biological products through FY 2002. The Act establishes fees for applications, establishments, and approved products. The user fees have enabled the Agency to improve its performance for drug review and approval times. The median user-fee PLA approval time decreased from 22.5 months in FY 1994, to 14.5 months in FY 1996.

FDA has met or exceeded its PDUFA performance goals thus far. Meeting with sponsors early in the drug development process makes the process more efficient for industry and the Agency. Product license applications (PLAs) are of better quality and there are fewer refuse-to-file decisions. The number of user-fee PLAs that were refused filing declined from three in FY 1994 to zero in FY 1997.

FDA has initiated programs designed to make the application review process more efficient. One such initiative is the Managed Review Process. The Managed Review Process incorporates concepts of project

FY 1999 Performance Goal Highlights

1. Review 90% of standard original NDA/PLA/BLA submissions within 12 months of receipt (30% within 10 months); and 90% of priority original NDA/PLA/BLA submissions within 6 months of receipt.
2. Review 90% of standard efficacy supplements within 12 months of receipt (30% within 10 months); and 90% of priority efficacy supplements within 6 months of receipt.
3. Review 90% of manufacturing supplements within 6 months of receipt, and review 30% within 4 months of receipt.
4. Review 90% of Class 1 resubmitted original applications within 4 months of receipt (50% within 2 months); and review 90% of Class 2 resubmitted original applications within 6 months of receipt.

management with the goal of producing high quality reviews in a timely manner. The system includes establishing specific time frames with interim milestones for the evaluation of both establishment and product license applications.

The Quality Assurance Staff has oversight responsibility for both the Clinical Hold and the Refuse-to-File Oversight committees, thereby bringing a program management review and perspective to the process. Review of these actions by the respective committees ensures that high review standards and consistency of action are maintained. This program will be expanded to examine IND and PLA letters for consistency and quality. The assessments will be designed to enhance the Program's reviewer training programs and aid management to make corrections.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

FY 1999 Performance Goal Highlights

1. Review and act on 70% of complete blood bank and source plasma PLA/BLA submissions and PLA/BLA Major supplements within 12 months after submission date.
2. Review and act on 60% of complete blood bank and source plasma ELA Major supplements within 12 months after submission date.

Cluster: Blood, Tissues, and Other Biological Products

\$35,587,000 FTEs: 424

Cluster Rationale: The mission of the Blood Program is to ensure that blood, blood products, biotechnology-derived hematologics, and devices associated with their manufacture and use are safe, effective, and adequately labeled.

The blood supply is critical to the nation's health care system, and the United States has the safest blood supply in the world. Each year approximately 12 million blood units are drawn from volunteer donors for use in more than 3.5 million Americans. FDA vigorously continues to strengthen its efforts to protect the nation's blood supply, and to

minimize any risk to patients acquiring the human immunodeficiency virus (HIV), hepatitis, Creutzfeldt-Jakob disease (CJD), and other bloodborne diseases.

Resources, Approaches, Processes, Skills, and Technology: FDA reviews and evaluates pre-marketing license applications for blood establishments and blood products. The Agency also conducts research of blood and blood products pertinent to its regulatory mission. FDA will continue to develop regulations to screen and test donors for infectious diseases. FDA will also extend its current blood oversight, and regulation revitalization and reinvention project. The major areas to be addressed include: development of the biologics license application (BLA) as it applies to blood establishments; development of Agency-wide goals and direction; coordination of Agency-wide resources to protect the blood supply; and revitalization and rewriting of blood regulations.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

FY 1999 Performance Goal Highlights

1. Assure that the domestic biologics manufacturers and repacking establishments inspected by the FDA achieve a 90% rate of conformance with FDA requirements.
2. Increase compliance of plasma fractionator establishments to 80%.

Cluster: Biologics Compliance

\$24,233,000 FTEs: 159

Cluster Rationale: FDA is required by law to conduct biennial inspections of all licensed establishments to determine compliance with current good manufacturing practice (GMP) regulations and to ensure compliance with applicable product and establishment standards, and license commitments. In addition, FDA inspects all manufacturing facilities which are unlicensed and under contract to a licensed establishment. FDA conducts biomedical research inspections to review pivotal clinical trial data and inspections of new tissue-cellular-based products.

Resources, Approaches, Processes, Skills, and Technology: In addition to enhancing quality assurance procedures in blood banks, FDA will be defining new strategies for blood bank inspections based

on control processes for critical production points; conducting training programs for inspectors to implement the new approaches; conducting workshops to clarify Agency expectations for industry; and evaluating the need for changes in the error and accident reporting requirements. FDA will continue to improve donor eligibility criteria and deferral programs. It will also continue studies to assess the effectiveness of donor interview and education programs and will coordinate a national effort to address concerns regarding donor deferral registries. FDA will continue to collaborate closely with other government and non-government regulatory organizations to assure that all policies are mutually consistent in guarding the safety of the nation's blood supply.

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BIOLOGICS PERFORMANCE GOALS

Strategic Goal
Area: **PREMARKET REVIEW**

Cluster: **Prescription Drug User Fee Act (PDUFA)**

1. *Review and act on 90% of standard New Drug Applications (NDA) and Product License Applications/Biologics License Applications (PLA/BLA) filed within 12 months after receipt (30% within 10 months of receipt); and review and act on 90% of priority NDA and PLA/BLA submissions within six months of receipt.*

Agency
Strategies: Streamline application reviews.

Data Sources: CBER's Biologics Regulatory Management System (BRMS).

Baseline Data: *Standard applications:*

FY 1993: 86%
FY 1994: 100%
FY 1995: 100%
FY 1996: 100%

Priority applications:

Under development. Data showing percent reviewed within six month period will be available mid-FY 1998.

2. *Review and act on 90% of standard efficacy supplements within 12 months of receipt (30% within 10 months of receipt); and review and act on 90% of priority efficacy supplements within six months of receipt.*

Agency
Strategies: Streamline application reviews.

Data Sources: CBER's Biologics Regulatory Management System (BRMS).

Baseline Data: *Standard applications:*

FY 1993: 55%
FY 1994: 83%
FY 1995: 100%

FY 1996: 88%

Priority applications:

Under development. Data showing percent reviewed within 6 month period will be available mid-FY 1998.

3. *Review and act on 90% of manufacturing supplements filed within six months of receipt, and review and act on 30% of manufacturing supplements requiring prior approval within four months of receipt.*

Agency Strategies: Streamline application reviews.

Data Sources: CBER's Biologics Regulatory Management System (BRMS).

Baseline Data: FY 1993: 53%
FY 1994: 85%
FY 1995: 94%
FY 1996: 98%

4. *Review and act on 90% of Class 1 resubmitted original applications within four months of receipt (50% within two months of receipt); and review and act on 90% of Class 2 resubmitted original applications within six months of receipt.*

Agency Strategies: Streamline reviews. Inform and assist product sponsors.

Data Sources: CBER's Biologics Regulatory Management System (BRMS).

Baseline Data: Under development. Data showing percent reviewed within 6 month period will be available mid-FY 1998.

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Strategic Goal Area: **PREMARKET REVIEW**

Cluster: **Blood, Tissues, and Other Biological Products**

1. *Review and act on 70% of complete blood bank and source plasma PLA/BLA submissions and PLA/BLA Major supplements within 12 months after submission date.*

Agency Strategies: Streamline reviews.

Data Sources: CBER's Biologics Regulatory Management System (BRMS).

Baseline Data: *Complete submissions:*
FY 1993: 34%
FY 1994: 43%
FY 1995: 84%
FY 1996: 95%

Major supplements:

Under development. Data showing percent reviewed within 12 month period will be available mid-FY 1998.

2. *Review and act on 60% of complete blood bank/source plasma Establishment License Applications (ELA) Major supplements within 12 months after submission date.*

Agency Strategies: Streamline reviews.

Data Sources: CBER's Biologics Regulatory Management System (BRMS).

Baseline Data: Under development. Data showing percent reviewed within 12 month period will be available mid-FY 1998.

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Strategic Goal Area: **POSTMARKET ASSURANCE**

Cluster: **Biologics Compliance**

1. *Assure that FDA inspections of domestic biologics manufacturers and repacking establishments in conjunction with the timely correction of serious deficiencies identified in these inspections result in a high rate of conformance (at least 90%) with FDA requirements by the end of the fiscal year.*

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Field Data Systems.

Baseline Data: Prior compliance performance measures have been essentially counts of activities at various points along the enforcement continuum-i.e., number of inspections, violative inspections, warning letters, prosecutions, etc. This new measure strives to integrate the results of these activities into an end-of-the-year statement about the compliance of this specific industry sector. A prototype of the new measure will be generated in FY 1998.

2. *Increase the percentage of plasma fractionator establishments in compliance with current good manufacturing practices (CGMPs) to 80%.*

Agency Strategies: Inform and assist firms to achieve compliance. Target high priority domestic and import risks. Maintain inspection visibility.

Data Sources: ORA's PODS.

Baseline Data: There are 26 foreign and domestic fractionator establishments. In FY 1996, 12 establishments were inspected and 9 were in compliance (75%).

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ANIMAL DRUGS AND FEEDS

PROGRAM RESOURCES (FY 1999)

| Cluster | \$000 FTEs |
|---------------------------|------------|
| 1. NEW ANIMAL DRUG REVIEW | 18,906 186 |

| | | |
|-------------------------|----------------|--------------|
| <i>FSI</i> | [900] | [2] |
| 2. POSTMARKET ASSURANCE | 26,068 | 257 |
| <i>FSI</i> | [6,300] | [14] |
| <hr/> | | |
| PROGRAM TOTAL | 124,428 | 1,076 |
| <i>[FSI]</i> | [7,200] | [16] |

Note: Clusters 1 and 2 include FSI activities. Base resources allocated specifically to FSI in FY 1997 and incremental resources allocated to FSI in FY 1998 and FY 1999 appear in brackets.

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STRATEGIC FUTURE (FY 1999-2004)

The Animal Drugs and Feeds Program's performance goals will support the Agency's overall strategies as follows:

The Animal Drugs and Feeds Program strategic goal is to increase the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, improve animal productivity, and do not compromise public health.

In order to increase the availability and diversity of safe and effective products, the Animal Drugs and Feeds Program will expedite and facilitate the approval of new animal drugs by implementing the Animal Drug Availability Act of 1996 (ADAA) [1] and our reinventing government (REGO) initiative. The Animal Drugs and Feeds Program will inform and assist product sponsors throughout the approval process starting with the Pre-submission Conference. Focus will be on informing and assisting firms in complying with the new legislation and streamlining the product review process by continuing the implementation of the phased review process. Streamlining efforts will be focused on reducing the overall time required for drug development from product conception by the drug sponsor through the Investigational New Animal Drug phase to the New Animal Drug approval. New performance measures will be developed to assess progress toward our goals. Better automated information systems, including those supporting electronic submission of applications by sponsors, will be developed to facilitate and expedite the review process.

In order to enable the marketing of effective animal drugs and food additives, the Animal Drugs and Feeds Program will take regulatory actions to remove unapproved drugs and food additives from the market. The Animal Drugs and Feeds Program will also ensure that

approved products provide for safe human food products derived from animals as well as ensure quality health care of animals. The surveillance plans will enhance the ability of FDA to monitor adverse reactions to veterinary products and to detect animal and public health risks such as drug residues in meat, eggs or milk. Partnerships with other government agencies, state and local government, and regulated industry as well as expanded educational programs will enable the Animal Drugs and Feeds Program to maintain the current level of compliance.

Assumptions: The FY 1999 performance goals are contingent on the Food Safety Initiative. It is also assumed that USDA will continue to support their national sampling plan and forward violations to FDA. The target levels of the performance goals are based on the assumption that there will be no additional streamlining decreases.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

FY 1999 Performance Goal Highlights

1. Implement the Animal Drug Availability Act including the Veterinary Feed Directive (VFD).
2. Begin automating the review process.
3. Increase risk assessment for anti-microbial products by 10%.

Cluster: New Animal Drug Review

\$18,906,000 FTEs: 186

Cluster Rationale: Safe and effective veterinary drugs are essential for improved production of food-producing animals, as well as for the health and well-being of both companion and food producing animals. Improved production of food-producing animals has a positive economic effect on the agricultural community which increases the availability of animal products for human consumption. The New Animal Drug Review is part of the approval process and supports the overall mission of both FDA and the United States Department of Agriculture to ensure that animal-derived products are safe for human consumption. In support of the safety determination for edible products from food producing animals, risk assessment is becoming an important aspect of the approval process. The Animal Drugs and Feeds Program, through the New Animal Drug Review process, works toward the increased availability of new animal drugs.

The New Animal Drug Review Process is a natural cluster because it groups the pre-approval activities of the Animal Drugs and Feeds Program. It includes goals related to the implementation of the Animal Drug Availability Act (ADAA) which inform and assist product sponsors as well as goals related to new processes that have been developed to streamline the approval process under FDA's three reinventing government (REGO) initiatives. It also includes goals related to risk assessments and antimicrobial products as part of the pre-approval food safety evaluation.

The immediate outcome from these performance goals will be a decrease in the developmental time and costs associated with research studies and other drug approval regulatory requirements. Pre-submission conferences and availability of the Center for Veterinary Medicine (CVM) guidelines through the Internet (CVM Home Page) and workshops will increase industry efficiency and thereby reduce overall developmental costs. Phased review will provide more timely feedback as well as "early detection" of application deficiencies.

The streamlined processes will decrease overall review time and thereby increase the availability of safe and effective animal drugs. Phased review, coupled with improved information systems such as electronic submission of applications, will allow FDA to perform review activities more efficiently. This will enable the agricultural community to provide animal-derived products more effectively and possibly at a lower cost due to the reduced animal drug developmental costs being reflected in lower costs to purchasers.

A third immediate outcome is increased availability of drugs to treat companion animals, thereby increasing their life span and the quality of life. Studies have shown that companion animals have a positive effect on the quality of life of selected segments of the human population. Companion animals are used to increase independence of individuals with disabilities such as guide dogs for the blind, working dogs for the deaf, and a variety of animals assisting physically-challenged individuals.

A primary ultimate outcome is safe animal products for human consumption. Veterinarians and the agricultural community need animal drugs to ensure a safe food supply. New drugs are needed as disease causing agents mutate and become resistant to current drugs. Risk assessment related to antimicrobial products contributes to risk management decisions and availability of safe and effective animal drugs. Human consumption of safe animal products contributes to a balanced diet, which contributes to better health.

This cluster supports the Agency's premarket review goal area, specifically the strategies of informing and assisting product sponsors and streamlining reviews. Information dissemination is critical to the

successful implementation of the ADAA and our REGO initiatives and the development of a collaborative atmosphere which benefits drug sponsors, FDA reviewers, taxpayers, and the general public.

Resources, Approaches, Processes, Skills, and Technology:

Resources are primarily devoted to new animal drug review, but also include surveillance activities in the field and research that supports the review process.

A sponsor notifies CVM about the development of a new animal drug. CVM works with the sponsor to set up a pre-submission conference. The conference can be conducted "in-person" or by teleconference, or in the future, by video conference. Information exchange continues throughout the research and development process. As the sponsor completes a technical section (the different pieces of a New Animal Drug Application), it is submitted to CVM for review. The technical sections include target animal safety and effectiveness, manufacturing methods and control chemistry, residue chemistry and regulatory methods, human food safety, and environmental safety.

Routine postmarket surveillance activities and special surveys are conducted to assure that sponsors are in compliance with regulations intended to ensure data integrity and good manufacturing practices. Pre-approval inspections are conducted when needed, to enhance understanding and confirm that the sponsor has the ability to produce a safe and effective product.

Research is an essential element in the approval process. Method validation studies are necessary in approving applications for new drugs for food animals. In addition to methods validation, analytical methods development research improves the effectiveness of surveillance activities by providing more rapid and accurate procedures to detect and quantitate chemical substances in foods. Information system development improves the ability of primary reviewers to access Agency and sponsor data used in the review process.

New Animal Drug Review activities are supported by scientific research, data collection, and analysis. Scientists provide guidance and assistance to industry, consumers, and other constituencies regarding regulatory interpretations related to animal drugs and feeds. They also serve as national experts by providing technical expertise for the development and harmonization of international specifications and standards in the area of veterinary medicine.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Postmarket Assurance

\$26,068,000

FTEs: 257

Cluster Rationale: The Postmarket Assurance Process is a natural cluster because it groups the postmarket activities of the Animal Drugs and Feeds Program. Through improving/enhancing our compliance strategy FDA will reduce the availability of unsafe animal drugs. Through the use of the National Surveillance System, we will monitor current patterns and take action to contain antimicrobial resistance. Through development of partnership relationships with industry and the states, we will implement the ADAA through new regulations, development of educational initiatives, and, as needed, the development of enforcement strategies to assure public safety. The immediate outcome will be the on-going establishment and updating of baseline data to:

FY 1999 Performance Goal Highlights

1. Assure that the domestic animal drug and feed manufacturing establishments inspected by FDA achieve a 90% rate of conformance with FDA requirements.
2. Improve monitoring of antibiotic resistant bacteria.
3. Implement BSE regulations.

1. establish standards which will be used to evaluate the compliance of marketed products;
2. identify emerging patterns of antibiotic resistance; and
3. direct resources toward high risk product areas.

An intermediate outcome will be to achieve desired levels of industry conformance and to ensure accurate and valid information that can be interpreted in an appropriate, consistent, and balanced fashion. The early identification of emerging issues will allow agencies to focus education efforts in the human and veterinary medical communities appropriately.

The ultimate outcome is the assurance that marketed animal drugs and food additives provide for safe food products derived from animals and ensure quality health care of animals. Postmarket surveillance is an important aspect of assuring continual safe animal products for human consumption.

This cluster supports the Agency's postmarket assurance goal area, specifically the strategies to develop science-based product and process standards, improve surveillance and follow-up on adverse events, maintain inspection visibility, and inform and assist firms to achieve compliance.

Resources, Approaches, Processes, Skills, And Technology:

Resources are primarily devoted to monitoring and surveillance activities, including FDA field inspections/investigations, data review

and analysis, educational initiatives, scientific research, and development of compliance and enforcement strategies. FDA is notified about potential postmarket problems via one or more of its early warning systems. FDA reviews National Surveillance System data, Adverse Drug Reports (ADRs), Establishment Inspection Reports (EIRs), Contamination Response System (CRS) data, Residue Violation Information System (RVIS), or other forms of communication. FDA then takes the appropriate action to address emerging issues, prevent or contain problems, and bring the animal drug industry into compliance.

Routine postmarket surveillance activities and special surveys are conducted to assure that sponsors are in compliance with regulations designated to ensure data integrity and good manufacturing practices. In FY 1999, FDA will continue activities initiated in FY 1998 to ensure that industry complies with the regulations to protect animals from transmissible degenerative neurological diseases, and to minimize any potential risk that such diseases could be transmitted from animals to humans.

In addition, FDA partners with other Federal and state agencies, our stakeholders, and regulated industry to develop and sponsor workshops, symposia, and publications with a focus on prevention in order to assure the public that accurate information is disseminated and that marketed animal drugs and feeds are safe and effective. Collaborative investigational contracts to identify farm management practices will also contribute to the FDA's effort to reduce the occurrence of foodborne disease.

Research is an essential element in postmarket assurance. Research studies are necessary in order to develop methods for detecting drugs and drug residues that may be present in food products derived from animals. In addition to methods development, analytical methods development research improves the effectiveness of monitoring for antibiotic resistance patterns and provides more rapid and accurate procedures to detect and quantify chemical substances in foods.

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ANIMAL DRUGS AND FEEDS PERFORMANCE GOALS

Strategic Goal Area: **PREMARKET REVIEW**

Cluster: **New Animal Drug Review**

1. Improve application processing by implementing ADAA legislation and CVM REGO initiatives, including the Veterinary Feed Directive (VFD), by establishing and/or revising regulations and guidance documents.

Agency Inform and assist product sponsors.

Strategies:

Data Sources: CVM's priority project tracking system.

Baseline Data: Due to new legislative approach, application processing baselines are not yet available, but will be reestablished in FY 1998 - FY 1999.

2. *Improve application processing time by implementing electronic submission for key components of the investigational new animal drug application process.*

Agency Strategies: Streamline reviews.

Data Sources: CVM's priority project tracking system.

Baseline Data: Due to new legislative approach, application processing baselines are not yet available, but will be reestablished in FY 1998 - FY 1999.

3. *Increase the number of antimicrobial product risk assessments by 10% in order to increase the assurance that food derived from animals and animal products is safe for human consumption.*

Agency Strategies: Streamline reviews.

Data Sources: CVM's priority project tracking system.

Baseline Data: Risk assessment baselines will be established in FY 1998.

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Strategic Goal Area: POSTMARKET ASSURANCE

Cluster: Postmarket Assurance

1. *Assure that FDA inspections of domestic animal drug and feed manufacturing establishments, in conjunction with the timely corrections of serious deficiencies identified in these inspections, result in a high rate of conformance (at least 90%) with FDA requirements by the end of the fiscal year.*

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Field Data Systems.

Baseline Data: Prior compliance performance measures have been essentially counts of activities at various points along the enforcement continuum - i.e., number of inspections, violative inspections, warning letters, prosecutions, etc. This new measure strives to integrate the results of these activities into an end-of-the year statement about the compliance status of this specific industry sector. A prototype of the new measure will be generated in FY 1998.

2. *Assure that food derived from animals and animal products is safe for human consumption by increasing the number of human and animal isolates in the National Antimicrobial Monitoring Program database.*

Agency Strategies: Improve surveillance and follow-up on adverse events.

Data Sources: FDA-CDC-USDA National Antimicrobial Monitoring Program.

Baseline Data: FY 1996: 1000 Human Isolates, 1000 Animal Isolates.

3. *Protect public health (human) and animal health by ensuring compliance with good manufacturing practices including the newly implemented BSE (Mad Cow Disease) regulation through education, regulatory inspections and industry/Federal/state partnerships.*

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Field Information System.

Baseline Data: To be developed in FY 1998.

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1. ADAA substantially alters the way FDA regulates and approves animal drugs and medicated feeds by granting the authority to exercise considerable flexibility in regulatory decision making. During the implementation phase, which includes promulgation of regulations through notice and comment rulemaking, FDA is continuing the dialogue with stakeholders that began prior to the passage of the ADAA.

MEDICAL DEVICES AND RADIOLOGICAL HEALTH

PROGRAM RESOURCES (FY 1999)

| | Cluster | \$000 | FTEs |
|----|---|--------|------|
| 1. | PREMARKET | 55,035 | 620 |
| 2. | SCIENCE, TECHNOLOGY AND STANDARDS | 10,890 | 121 |
| 3. | POSTMARKET | 14,590 | 163 |
| 4. | COMPLIANCE | 38,152 | 416 |
| 5. | MAMMOGRAPHY QUALITY STANDARDS ACT | 24,580 | 111 |
| 6. | RADIATION CONTROL FOR HEALTH AND SAFETY ACT | 12,707 | 139 |

PROGRAM TOTAL

155,955 1,569

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***STRATEGIC FUTURE
(FY 1999-2004)***

The FDA Modernization Act of 1997 requires FDA to conduct more timely and interactive application reviews, improve the quality and timeliness of postmarket surveillance data, expand participation in international harmonization activities, and improve information and education for industry and health professionals. In order to implement these mandates, FDA will identify and concentrate resources on high-risk, high-impact products or work areas, those where its direct intervention helps consumers and health care professionals the most. Despite current and anticipated budget constraints, resources will be redirected; and while some key areas will be increased, some low-risk product areas will be decreased. Acceptable alternatives to direct FDA involvement will be implemented while, at the same time, adequate consumer protection will be assured.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

FY 1999 Performance Goal Highlights

1. Complete 50% of PMA first actions within 180 days.
2. Complete 90% of 510(k) first actions within 90 days. Expand third party 510(k) reviews and complete FDA action on 55% of them within 30 days.

Cluster: Premarket

\$55,035,000 FTEs: 620

Cluster Rationale: Prior to marketing a device, manufacturers must seek FDA safety and effectiveness approval of their products. FDA is responsible for assigning marketed medical devices to a regulatory category (Class Ió General Controls; Class IIóSpecial Controls; Class IIIóPremarket Approval). FDA reviews three types of industry submissions:

1. Premarket Notifications (510(k)s)óproducts substantially equivalent to products on the market;

2. Investigational Device Exemptions (IDEs) of devices used in clinical investigations on human subjects; and
3. Premarket Approvals (PMAs) of devices that support or sustain human life, which present a potential, unreasonable risk of illness or injury.

In FY 1999, FDA will continue reengineering the device review process with emphasis on the new requirements of the Modernization Act, while striving to maintain a stable, predictable level of review performance. When the redesigned review process is fully implemented, FDA anticipates enhanced performance levels beyond FY 1999. The outcome of this strategy will be more rapid access to safe and effective medical devices.

The Modernization Act also requires the following:

Presubmission consultations -- Sponsors planning to submit a premarket approval application (PMA) can submit a written request to FDA for a meeting to determine the type of information (valid scientific evidence) that is necessary to support the effectiveness of their device. FDA must meet with the requester and communicate the Agency's determination of the type of data that will be necessary to demonstrate effectiveness in writing within 30 days after the meeting.

Humanitarian device exemptions -- The Act requires FDA to act within 75 days on requests for exemption from effectiveness requirements for humanitarian devices (devices for patient populations under 4,000).

"De novo" classification requests -- An applicant of a premarket notification submission, (510(k)), who receives a not substantially equivalent (NSE) determination, placing the device into a Class III category, can request classification of the product into Class I or II. Within 60 days from the date the written request is submitted to FDA, the Agency must classify the device by written order. If FDA classifies the device into Class I or II, the applicant has then received clearance to market the device. This device can be used as a predicate device for other 510(k)s. However, if FDA determines that the device will remain in the Class III category, the device cannot be marketed until the applicant has obtained an approved premarket approval application (PMA) or an approved investigational device exemption (IDE).

Resources, Approaches, Processes, Skills, and Technology: FDA is redirecting resources to high-risk, high-impact product areas where direct intervention helps consumers and health care professionals most. This may increase resources in key areas and decrease resources in areas that pose lower risk to the public or where FDA's direct involvement is not essential.

Resources involved in this effort include support from various center organizations: Office of Science and Technology will perform scientific

reviews and assist in establishing standards; Office of Systems and Management will provide information system support; Office of Surveillance and Biometrics will provide statistical reviews; and, FDA's Office of Regulatory Affairs will assist with pre-approval inspections and data integrity verification.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

FY 1999 Performance Goal Highlights

1. Recognize over 50 standards for use in application review and update the list of recognized standards.

Cluster: Science, Technology and Standards \$10,890,000 FTEs: 121

Cluster Rationale: Science, technology and standards activities are directed to improve science support to the device review process. The Modernization Act requires FDA to recognize and use standards in application review. In addition, the Act requires FDA to expand its participation in international harmonization of standards. FDA plans to increase the use of consensus standards developed by such national and international organizations as the American National Standards Institute (ANSI) and the International Standards Organization (ISO) to improve pre-market approval times.

The science, technology and standards cluster is focused on providing direct science support to the device approval process and to promote increased acceptance of consensus standards in support of FDA product review and evaluation activities.

Resources, Approaches, Processes, Skills, and Technology:

Resources are being utilized to increase participation of science expertise in the review and approval of high-risk medical devices during pre-market review. In addition, efforts are underway to develop and promote consensus performance standards as guides in the design of safer and more effective medical products and to enhance the quality of regulatory decision making.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Postmarket

\$14,590,000 FTEs: 163

Cluster Rationale: FDA is responsible for monitoring the market for adverse effects of medical devices. FDA received over 93,000 post-market reports in FY 1997, including mandated reports from medical device manufacturers; voluntary reports from medical device professionals received through the problem

reporting program (MedWatch); and results of field inspections or investigations. FDA is currently managing the huge numbers of reports in three phases. During the first phase, the reports are screened, scanned for completeness and entered into the data management system. During the second phase the reports are analyzed for similar events, while judging severity and searching for trends. The final phase focuses on action, such as issuing safety alerts and notifications to users (health professionals and patients) warning them of concerns and advising them how to prevent future occurrences.

The Modernization Act authorizes FDA to evaluate the Sentinel program (which will develop representative samples of adverse events) and to discontinue 100 percent user facility reporting if the Sentinel program proves to be a viable alternative. The Sentinel system currently under development is based on the premise that a select group of highly trained reporting facilities can provide a statistical sample of adverse event reports that are representative of user facilities in general. FDA's postmarket cluster strategy is to improve postmarket reporting by improving data entry, utilizing new quality assurance mechanisms like the Sentinel program. This will make reporting more efficient, provide better public health protection through a reallocation of resources, and enable use of new tools like summary reporting, particularly where many reports address the same problem.

Resources, Approaches, Processes, Skills, and Technology: The major efforts in the post-market area are focused on the improvement of quality analysis of reported adverse events, including improvement of FDA's ability to analyze reports that lend themselves to aggregate reporting.

FY 1999 Performance Goal Highlights

1. Implement electronic reporting system for adverse events that will double the number of reports processed in summary form and improve safety alerts.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Compliance

\$38,152,000

FTEs: 416

Cluster Rationale: The compliance program enforces numerous regulations to protect the public from unsafe or ineffective medical devices or radiological products. The Modernization Act requires FDA to register foreign device establishments who produce products to sell in the U.S. FDA also informs and verifies that medical device firms are knowledgeable of and utilize good manufacturing practices (GMP).

Inspections of devices fall into three categories:

1. **Routine Surveillance Inspections** to determine compliance with FDA's good manufacturing practices;
2. **Targeted Inspections** for approval to market high-risk devices; inspections triggered by adverse reaction incidents; or product recalls; and
3. **Compliance Inspections** to collect evidence for pending enforcement actions.

Resources, Approaches, Processes, Skills, and Technology: The compliance program cluster is focused on improving enforcement actions by redirecting resources to high-risk devices such as implants. Additionally, compliance activities are providing an opportunity for increased utilization of good manufacturing practices by enhancing the body of knowledge and providing more training to field personnel.

Initiative

A complete priority model will be presented to the GMP advisory committee and, if accepted, the model will be documented in the field work plan and compliance programs.

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FY 1999 Performance Goal Highlights

1. Improve quality conformance of high-risk products like cardiovascular devices, by redirecting compliance priorities toward higher risk devices.
2. Assure that the domestic medical device manufacturing establishments inspected by FDA achieve a 95% rate of conformance with FDA requirements.

STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Mammography Quality Standards Act \$24,580,000 FTEs: 111

Cluster Rationale: The Mammography Quality Standards Act (MQSA) requires all mammography facilities to be certified by the Secretary of Health and Human Services as meeting the specific quality standards in the areas of equipment, personnel, quality assurance, record keeping, and reporting. FDA estimates that there are approximately 10,000 mammography facilities that are covered by the MQSA legislation.

Resources, Approaches, Processes, Skills, and Technology: The MQSA program cluster is directed to the certification of mammography facilities and to annual inspections to ensure that they remain in compliance with established quality standards, to reduce defects and to improve the quality of mammography in the United States.

Initiatives

Establishment and maintenance of a mammography information service in cooperation with the National Cancer Institute for women to obtain information about FDA-certified facilities in local areas. Maintain outreach programs including the publishing of a fact-based, quarterly newsletter, and the presentation of informative material at regional and national health professional meetings.

Assumption: That certification and quality assurance requirements as stated in the Act will be reauthorized and remain unchanged.

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FY 1999 Performance Goal Highlights

1. At least 97% of mammography centers meet key inspection standards.

STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

FY 1999 Performance Goal Highlights

1. Take action on 95% of high-risk electronic products within 30 days of radiation hazard discovery.

Cluster: Radiation Control for Health and Safety Act **\$12,707,000** **FTEs: 139**

Cluster Rationale: Under the Radiation Control for Health and Safety Act (RCHSA), FDA conducts an electronic radiation control program to assess the biological effects resulting from all types of radiation exposure, evaluate radiation emissions from electronic products,

conduct research to minimize exposure, and set and enforce radiation performance standards. Manufacturers of radiation-emitting products such as x-ray machines, lasers, microwave heating equipment, television and ultrasonic therapy equipment are required to submit initial reports, annual reports, and model change reports to FDA. In conjunction with its regulatory efforts, FDA carries on specialized programs to reduce patient exposure during diagnostic x-ray procedures by encouraging improved practice among health professionals and by developing new x-ray techniques. FDA makes continual checks to assure its efforts are such that the potential of radiation for service to mankind can be realized at minimum risk of harm. As new radiation-producing electronic products are developed, FDA evaluates them to ensure they are safe.

Resources, Approaches, Processes, Skills, and Technology: The RCHSA program cluster is focused on assuring minimal exposure to radiation from electronic products by assessing emissions, labeling, controls, and user practices. Safety of use is improved through enhancing the body of knowledge and providing information to researchers, industry, and users including medical practitioners, consumers and industrial workers. As technology progresses, the scope of products increases much faster than the knowledge of bioeffects. Adverse event reports, recalls, and noncompliance rates are monitored for adjustments in priorities. Personnel of multiple disciplines and specialized training, along with specialized test equipment, are utilized to assess bioeffects and safety, to enforce performance standards, to develop proposals for new standards, both regulatory and consensus, and to present recommendations to an advisory committee prior to publication of Federal Register notices. Interpretive policies are developed to permit greater flexibility in meeting requirements that are not critical to radiation safety.

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MEDICAL DEVICES AND RADIOLOGICAL HEALTH PERFORMANCE GOALS

FDA's medical device premarket strategy is to reengineer the device review process, redirect resources to high-risk and high-impact product areas, and decrease resources in areas that pose a lower risk or benefit. In the long run, this will improve timeliness for high-risk devices and maintain timeliness without sacrificing quality for low-risk devices. During FY 1998 and FY 1999, FDA is striving to maintain device review performance at FY 1997 levels, while expediting reengineering efforts.

Strategic Goal PREMARKET REVIEW

Area:

Cluster: **Premarket Review**

1. *Complete 50% of PMA first actions within 180 days.*

Agency Strategies: Streamline reviews.

Data Sources: Receipt cohort reports.

Baseline Data: FY 1996: 51% of first PMA actions completed within 180 days.
FY 1997: 50% (est.) of first PMA actions completed within 180 days.
1997: Past performance baseline is not comparable with FY 1999 goal because reengineering and the new statute redefine the review process.

2. *Complete 90% of 510(k) first actions within 90 days. Expand third party 510(k) reviews and complete FDA action on 55% of them within 30 days.*

Agency Strategies: Streamline reviews.

Data Sources: Receipt cohort reports.

Baseline Data: FY 1997: 98% of first 510(k) actions completed within 90 days of application submittal. Past performance baseline is not comparable with FY 1999 goal because reengineering and the new statute redefine the 510(k) population and review process.

Thirty-day FDA processing time for third party reviews is a new legislative requirement and no baseline data exists.

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Strategic Goal Area: **PREMARKET REVIEW**

Cluster: **Science, Technology & Standards**

1. *Recognize over 50 standards for use in application review and update the list of recognized standards.*

Agency Strategies: Develop science-based review standards.

Data Sources: Status of standard development.

Baseline Data: FDA currently recognizes one standard for use in device application review.

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Strategic Goal Area: **POSTMARKET ASSURANCE**

Cluster: **Postmarket Assurance**

1. *Double the number of low-risk postmarket reports received and processed in summary*

form. The total number of summary reports will be increased from 25,000 in FY 1998 to over 60,000 in FY 1999. This will be done by shifting postmarket reporting from a paper-intensive individual report system (receiving over 100,000 reports in FY 1996) to an alternate almost entirely electronic reporting system, yielding higher quality information using innovative surveillance methodology like auto screen and developing variances candidates.

Agency Strategies: Improve surveillance and follow-up of adverse events.

Data Sources: Medical Device Reports (MDR) and MedWatch (voluntary) adverse event reports.

Baseline Data: FY 1996: Over 100,000 total reports (10,000 in summary form)
FY 1997: Over 93,000 total reports (25,000 in summary form)

Note about Postmarket Reporting Baseline Data: FDA continues to establish policies and procedures for improved handling of postmarket notifications as well as to collaborate with industry on the development of study protocols for conducting postmarket surveillance studies. Computer programs are under development which not only allow for faster input and analysis of data, but also allow data to be aggregated and important health concerns to be identified and possible solutions developed in a more efficient manner. Currently, all reports are entered into the system within 48 hours.

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Strategic Goal Area: **POSTMARKET ASSURANCE**

Cluster: **Compliance**

1. Improve the quality conformance of high-risk products like cardiovascular devices by redirecting FDA compliance priorities toward higher-risk devices.

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Field Data Systems.

Baseline Data: FY 1996: About half of device compliance work focused on high-risk devices.

2. Assure that FDA inspections of domestic medical device manufacturing establishments, in conjunction with the timely correction of serious deficiencies identified in these inspections, result in a high rate of conformance (at least 95%) with FDA requirements by the end of the fiscal year.

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Field data systems

Baseline Data: FY 95%

1996:

Baseline Data: Prior compliance performance measures have been essentially counts of activities at various points along the enforcement continuum*i.e.*, number of inspections, violative inspections, warning letters, prosecutions, etc. This new measure strives to integrate the results of these activities into an end-of-the-year statement about the compliance status of this specific industry sector. A prototype of the new measure will be generated in FY 1998.

During FY 1997, compliance activities have been centered on the development of a risk-based, product-specific system. Appropriate high-risk medical devices to be included in the FY 1999 compliance cluster are being identified using a newly developed product-risk model. FDA is in the process of redirecting resources to high-risk devices. These devices will receive priority in compliance program planning. Baseline data are being established as the profile of current compliance activity and progress will be measured by comparison of the current profile with a snapshot taken at a future time.

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Strategic Goal Area: POSTMARKET ASSURANCE

Cluster: MQSA

1. *At least 97% of mammography centers meet key inspection standards, with less than 3% of facilities with Level I (serious) inspection problems.*

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: CDRH facility inspection reports.

Baseline Data: Under development. Resources are primarily devoted to maintaining quality assurance activities by conducting approximately 8,500 annual inspections and issuing 3,000 mammography facility certificates.

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Strategic Goal Area: POSTMARKET ASSURANCE

Cluster: RCHSA

1. *Improve response to significant risk electronic product radiation noncompliance by initiating regulatory actions and recalls for 95% of identified high-risk noncompliant or defective products within 30 days of discovery.*

Agency Strategies: Target high priority domestic and import risks. Inform and assist firms to achieve compliance.

Data Sources: Tracking databases, FDA and state laboratory and Inspection Industry guides, recall files, databases, legal case files.

Baseline Data: FY 1996: 95%. (See note)

Note about Radiation Program Baseline Data: Approximately 20 non-medical radiation incidents are received annually and approximately 500 medical incidents are reported through the MDR system.

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PROGRAM RESOURCES (FY 1999)

| Cluster | \$000 | FTEs |
|--|---------------|------------|
| 1. BUILD KNOWLEDGE BASES | 4,593 | 15 |
| 2. DEVELOP NEW STRATEGIES FOR THE PREDICTION OF TOXICITIES | 10,222 | 82 |
| 3. METHODS-, AGENT-, AND CONCEPT-DRIVEN RESEARCH | 16,764 | 128 |
| <i>[FSI]</i> | <i>[500]</i> | <i>[0]</i> |
| PROGRAM TOTAL | 31,579 | 225 |
| <i>FSI</i> | <i>[500]</i> | <i>[0]</i> |

Note: Cluster 3 includes FSI research activities. Incremental resources allocated specifically to FSI in FY 1999 appear in brackets. Base resources allocated to FSI in FY 1997 are not included.

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STRATEGIC FUTURE (FY 1999-2004)

The National Center for Toxicological Research (NCTR) is responsible for conducting peer-reviewed research that provides the bases for FDA to make sound science-based regulatory decisions and to promote the health of the American people through enforcement and compliance. NCTR achieves its mission by conducting fundamental and applied research designed to define the biological mechanisms of action underlying the toxicity of products regulated by the FDA. Specific aims of NCTR's research are to understand critical biological events in the

expression of toxicity and to develop methods to improve assessment of human exposure, susceptibility, and risk.

Over the next five years, NCTR will face an environment characterized by scientific challenges, continued advances in science and technology, increasingly complex regulatory challenges, and more constrained resources. Toxicologic research, often long-term and animal-intensive, has traditionally sought to understand the toxicity of chemicals through whole animal and cell culture exposure. Toxicologic data resulting from such studies have been used to predict risk to humans. The science of toxicology is moving away from its dependency on whole animal test systems that use large numbers of animals and seek relatively few endpoints. Although extrapolation from animal models to humans has been helpful, animal models have their limitations. Increasing evidence points to a need to identify and protect susceptible subpopulations of people because protecting the average person does not protect the large number of people who may be at higher risk from exposure to drugs, contaminated food, or other regulated products. In addition, the emphasis of toxicologic research has shifted from descriptive studies to studies that are designed to gain a better understanding of the biological mechanisms that cause toxic reactions.

New technologies have enhanced scientific assessment capabilities. The challenge is to apply these new technologies where appropriate to detect risk, ensure safety of FDA-regulated products, and to act in the best interest of the public. The FDA has expedited drug, device and biologic approval procedures to provide needed therapies to consumers more quickly. Continued improvement in this area is expected. Research results that improve the ability of FDA reviewers to evaluate product safety more rapidly and to estimate human risks more accurately are vital to continuing improvements in this area. The development of international trade alliances has increased the need to demonstrate scientifically, mechanisms of action that either provide for safety or improved risk assessment. To accomplish this, the FDA will require global scientific consultation and support.

Financial constraints and increases in the FDA's workload have increased the demand for more efficient, rapid, and economical test methods for assessing human risk in FDA headquarters and field laboratories. To respond to these challenges, the NCTR will continue to support the Agency's overall strategy by maintaining a high-quality, cost-effective research program that is responsive to the Agency's regulatory needs and supports FDA's ability to provide the desired level of consumer protection. NCTR will strive to find better and more economical means of protecting consumers and will focus its research efforts on the Agency's highest priority issues. The Center will continue

to leverage research resources through partnerships with other Federal agencies, national and international organizations, universities, and industry to best meet Agency needs.

NCTR, in partnership with other institutions, will develop methods for improving human risk assessment by applying a multi-disciplinary scientific approach to assess toxicity of compounds of regulatory significance to FDA. NCTR will work with scientists in the FDA product centers to develop a computerized system—a knowledge base—that will provide regulators with desktop access for interpretation of scientific data to predict adverse effects on human health. The utility of such a knowledge base is its ability to predict relevant chemical toxicity in humans and animals based on the structure of a drug or a chemical and its capability to reduce analysis time for compounds under review at the FDA.

NCTR is developing new predictive systems that will provide the use of state-of-the-art technology in answering difficult regulatory questions more quickly and with fewer resources. NCTR's new strategies for predicting toxicity include using new test systems that are based on understanding the smallest details of how a chemical produces a toxic effect; refining new and existing tests, as well as conducting studies that help reduce the uncertainty of extrapolating laboratory animal data to humans. Predictive systems will support FDA decisions regarding toxicity and will guide the design of subsequent toxicity research that will come ever closer to predicting human risk, quickly and less expensively.

NCTR will continue to collaborate and consult with scientists from FDA product centers and the Office of Regulatory Affairs in conducting agent-, method-, and concept-driven research to support the expanding regulatory focus of the FDA. Agent-driven research will focus on providing data when there is not an identifiable manufacturer or the scientific literature is weak on specific agents, such as estrogenic compounds, neurotoxins, mold contaminants on food, aquaculture therapeutics, and cosmetic exfoliants. Method-driven research will focus on developing and applying new toxicological and analytical test methods for more rapid, yet sensitive detection of bacterial pathogens and toxins in foods and drugs.

NCTR's research is guided by a comprehensive peer-review process. A Science Advisory Board composed of outside experts and FDA center science liaisons routinely evaluates and advises senior management on NCTR's quality and direction of each research area.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

Cluster: Build Knowledge Bases

\$4,593,000

FTEs: 15

Cluster Rationale: NCTR's highest priority is to assist FDA product centers make timely and cost-effective premarket review decisions by developing knowledge bases to aid in assessing human toxicity. FDA reviewers face an ever-increasing quantity and

complexity of data in new drug and product applications. Clearly, tools that can provide reviewers quick access to relevant scientific information and a capability for predicting toxicity would expedite review decisions. NCTR, in consultation with other FDA centers, government agencies and industries, is developing a knowledge base that will predict the toxicological activity of a compound by using biological indicators of damage, chemical structures via molecular modeling, and advanced mathematical and computer tools.

This cluster contains a single performance goal: to demonstrate a model toxicity knowledge base to support and expedite product review. Data developed at NCTR on the toxicity of estrogen and antiestrogen compounds is being coupled with data obtained through scientific collaborations (government, industry and academic) and published in literature and is being incorporated into a learning set for predictive computations. NCTR is adapting statistical techniques and applied computational techniques to construct this model knowledge base.

Knowledge base systems developed by FDA scientists can be used by reviewers and scientists outside of the FDA and the concept can be applied to other products being developed to improve human health. The proposed utility of knowledge bases is in their ability to enhance prediction of chemical toxicity in humans based on structure and known mechanistic interactions. Scientific data generated and published throughout the world can be incorporated into specific knowledge bases to answer complex questions within FDA, other government regulatory organizations, and industry, since the system will be made available publicly.

Resources, Approaches, Processes, Skills, and Technologies:

The Agency will need to maintain a strong scientific computing capability to devise ever-better tools to facilitate product approval. NCTR will use Center and on-site contractor resources (FTEs and dollars) from analytical chemistry, computational science, and genetic and reproductive toxicology to achieve this performance goal. The Center has an on-site information technology capability that provides expertise in the molecular modeling, structure activity relationships, 3-dimensional chemical structure and the selection and acquisition of

FY 1999 Performance Goal Highlights

1. Demonstrate a model toxicity knowledge base to support and expedite product review.

hardware and software for future developments and improvements. The novelty of this approach is the union of several disciplines focused on a common goal.

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STRATEGIC GOAL AREA: PREMARKET REVIEW

FY 1999 Performance Goal Highlights

1. Develop better biological assays to measure genetic changes and predict human genetic damage.
2. Conduct biochemical and epidemiological studies to define the basis for susceptibility of humans to the toxicity of regulated products.

Cluster: Develop New Strategies for the Prediction of Toxicity

\$10,222,000 FTEs: 82

Cluster Rationale: The human response to a toxic agent is a complex process. To adequately predict the adverse effects of human exposure to a toxic agent, a group of tests must be developed, validated, and applied. NCTR is using a multi-disciplinary approach to predict human toxicity and evaluate human risk using appropriate model systems. Human studies are conducted by our scientists in collaboration with peers at the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research, other agencies, universities, and medical centers around the world.

NCTR will use transgenic rodents (i.e., those carrying human genes) and human cell lines to predict human toxicity. NCTR researchers are continuing to develop laboratory methods that closely mimic human genetic response and predict human genetic damage. Use of the neonatal mouse assay will provide information about the toxicity of agents in a developing animal, information not provided by the more traditional studies in adult rodents. Moreover, traditional studies in adult rodents take longer than those conducted in the neonatal mouse assay. Other NCTR programs are using human data to understand the mechanisms of carcinogenesis particularly as they are related to individual susceptibility. International collaborative studies exploring human biomarkers will help to identify and potentially screen subpopulations at higher risk for developing certain types of cancer.

This will improve FDA's ability to determine and ultimately manage risk both in the United States and in collaboration with regulators and scientists throughout the world.

A single approach for risk assessment of both cancer and noncancer health outcomes is an important goal for FDA's risk assessment staff. Existing cancer and noncancer databases are being examined by FDA centers and are useful in helping to predict a broad spectrum of human risk. A new emerging project in the risk assessment area involves determining human risk from foodborne pathogens. This work is being proposed under the FDA Food Safety Initiative.

Resources, Approaches, Processes, Skills, and Technologies:

Information technology will help evaluate human models and monitor neonatal mouse studies. To accomplish these goals, a strong collaborative effort must continue to be fostered within the Agency and external partnerships must be encouraged, established, and maintained. Communication between scientists and reviewers, as exemplified in the most recent FDA Science Forum, will ensure that complex scientific issues are addressed quickly and that critical data are available to regulators.

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STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

FY 1999 Performance Goal Highlights

1. Support product review by developing faster, more accurate tests based on mechanisms of toxic action.
2. Develop rapid and sensitive foodborne bacteria methods for identifying pathogens, and microbial contaminants.

Cluster: Conduct Agent-, Concept-, and Method-Driven Research

\$16,764,000 FTEs: 128

Cluster Rationale: Most regulatory research begins as a precise exploration of a specific agent, a concept, or the use of a particular method. Once techniques are developed, these novel approaches can be applied to answer compelling questions of human health and safety. This cluster includes two performance goals that address the Agency strategy of developing science-based product and process standards.

Agent-driven research supported through an interagency agreement with the National Institute for Environmental Health Sciences (NIEHS)/ National Toxicology Program (NTP) has permitted NCTR to enhance the rodent bioassay to include the use of studies based on mechanisms of toxic action to improve bioassay interpretation and potentially speed up product review. Currently, NCTR is conducting special studies on four compounds of special concern to FDA: chloral hydrate, fumonisin B1, malachite green, and urethane in the presence of alcohol. Work is underway to develop testing protocols for the widely used skin exfoliants, alpha hydroxy acids. NCTR has started long-range multi-generation studies of compounds that disrupt normal endocrine function. These studies are designed to provide data on how estrogens and anti-estrogens may affect the developing fetus.

The Agency's need for state-of-the-art quantitative identification of toxic agents to strengthen the Agency's postmarket assurance is the basis of NCTR's method-driven research effort. In collaboration with FDA's Center for Food Safety and Nutrition (CFSAN), and as part of the Food Safety Initiative, NCTR is developing methods to identify microorganisms in food and to assess whether these microorganisms are undergoing change, thus becoming more virulent.

Research within this cluster capitalizes on partnerships with other FDA centers and with other agencies such as NIEHS and the United States Department of Agriculture (USDA). Regular meetings of scientific experts are held to develop a consensus on the best approach to take in improving the science-based process for the Agency.

Resources, Approaches, Processes, Skills, and Technologies: To accomplish these goals, NCTR needs continued review and input by other FDA centers, the Office of Regulatory Affairs, and outside experts to encourage and promote FDA-relevant research. National Toxicology Program studies require NCTR to maintain an accredited animal facility that includes a quality assurance staff, pathology capabilities, computerized record keeping, and high-quality animal husbandry and diet preparation support.

FDA's Science Board emphatically affirmed the need for a vigorous, high quality intramural program of scientific research which will provide the essential foundation of sound regulatory policy and performance. It was their position that such a program would ensure that the FDA is, and will continue to be, best positioned to carry out its statutory responsibilities.

Research conducted within this cluster requires a broad range of scientific expertise (i.e., analytical chemistry, microbiology, biochemistry, molecular biology, and biometry). Scientists within NCTR work collaboratively with Agency peers and in partnership with other agencies via interagency agreements and with industry via cooperative

research and development agreements to achieve the outcomes desired.

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH PERFORMANCE GOALS

Strategic Goal Area: **PREMARKET REVIEW**

Cluster: **Build Knowledge Bases**

1. *Demonstrate a model toxicity knowledge base to support and expedite product review.*

Agency Strategies: Develop science-based standards; Streamline reviews.

Data Sources: Evaluation of the prototype Estrogen Knowledge Base by FDA reviewers.

Baseline Data:

| | |
|----------|---|
| FY 1995: | A knowledge base strategy was developed. |
| FY 1996: | Computer hardware and software were procured and installed and systems integration was completed. |
| FY 1997: | Prototype presented at FDA Science Forum. |

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Strategic Goal Area: **PREMARKET REVIEW**

Cluster: **Develop New Strategies for the Prediction of Toxicity**

1. *Develop better biological assays to measure genetic changes and predict human genetic damage.*

Agency Strategies: Develop science-based standards; Streamline reviews.

Data Sources: FDA product center liaisons confirm data from these studies beneficial to evaluate human health concerns.

Baseline Data:

| | |
|----------|--|
| FY 1994: | Completed genetic toxicity evaluation of the pediatric sedative, chloral hydrate, in human transgene system. |
| FY 1995: | Evaluated programmed cell death (apoptosis) induced by chloral hydrate and tamoxifen. |
| FY 1996: | Expanded number of endogenous and exogenous reporter gene systems. |
| FY 1997: | Conducted genetic screening and evaluated additional toxicity induced outcomes (e.g., cell death and mutagenesis) and their relationship to DNA adducts. |

2. *Complete biochemical and epidemiology studies to define the basis of susceptibility of*

humans to the toxicity of regulated products.

Agency Strategies: Develop science-based standards; Streamline reviews.

Data Sources: Human biomarker monitoring using chemical and epidemiologic studies which characterize biomarkers of cancer for use in risk assessment.

Baseline Data: FY 1995: Developed scientific staff to address extrapolation of toxicity data.
FY 1996: Developed world-wide collaboration effort to measure biomarkers of cancer.
FY 1997: Studies underway to use molecular biomarkers in clinical studies and identify subpopulations at increased risk.

3. *Develop modeling tools to predict better risk for cancer, reproductive, developmental, neurological, genetic, and acute toxicological outcomes.*

Agency Strategies: Develop science-based standards; Streamline reviews.

Data Sources: Confirm the value of a model risk assessment procedure for cancer, reproductive, developmental, neurological, genetic and acute toxicological endpoints via publication and peer review evaluation.

Baseline Data: FY 1994: Worked with CDER on statistical guidance for design analysis and interpretation of animal tumorigenicity studies.
FY 1995: Participated in national and international conferences and committees on risk assessment procedures.
FY 1996: Developed and analyzed an approach to safely assess carcinogenic, reproductive, developmental, neurological, genetic and acute toxicology endpoints.
FY 1997: Concept was reviewed by an outside group of experts and prepared for publication.

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Strategic Goal Area: **POSTMARKET ASSURANCE**

Cluster: **Conduct Agent-, Concept-, and Method-Driven Research**

1. *Support product review by developing faster, more accurate tests based on mechanisms of toxic actions.*

Agency Strategies: Develop science-based product and process standards.

Data Sources: Results of the bioassays and mechanistic studies on high priority FDA compounds are available to FDA reviewers to assist in risk assessment.

Baseline Data: FY 1994: Rangefinding study on chloral hydrate completed. Acute toxicity study on fumonisin B1 initiated.
FY: Chronic bioassay (2-year studies) started on chloral hydrate

1995: and fumonisin B1.
 FY Two new compounds of interest to FDA were nominated,
 1996: malachite green and urethane in the presence of alcohol.
 FY Complete dosing regimen for two year chronic bioassay on
 1997: chloral hydrate and Fumonisin B1. Rangefinding studies on
 genistein, methoxychlor and nonylphenol were initiated plus a
 multi-generation study of endocrine disruptors was initiated.
 Phototoxicity assessment of alpha hydroxy acids was
 nominated for study.

2. *Develop rapid and sensitive methods for identifying pathogens, foodborne bacteria, and microbial contaminants.*

Agency Strategies: Develop science-based product and process standards.

Data Sources: Complete validation of PCR methods and initiate transfer to other FDA centers. Propose methods for Bacteriological Analytical Manual.

Baseline Data: FY Developed species-specific DNA probes for rapid detection of
 1994: anaerobic bacteria.
 FY Developed PCR and Mass Spectrometry procedures to detect
 1995: and identify major foodborne bacteria fungi of FDA concern.
 FY Applied 13 sets of DNA primers to the identification of 11
 1996: foodborne pathogens.
 FY Developed new protein based mass spectral techniques to
 1997: identify mutant bacteria.

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TOBACCO

PROGRAM RESOURCES (FY 1999)

| Cluster | \$000 FTEs |
|----------------------|-------------------|
| 1. TOBACCO | 134,000 50 |
| PROGRAM TOTAL | 134,000 50 |

STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Tobacco

\$134,000,000 FTEs: 50

Cluster Rationale: Reducing the use of tobacco by young people is an enormous undertaking with potential for great public health outcomes. Given the early stage of implementation of FDA's regulation of tobacco products and the court challenges to FDA's jurisdiction and rule, a single cluster is appropriate.

On August 23, 1996, President Clinton approved FDA's final rule, regulating nicotine-containing tobacco products. The final rule would limit the availability and appeal of tobacco products to younger people. It would limit the access that young people have to tobacco products by setting a minimum age of purchase, requiring that retailers check a photo identification of all customers under the age of 27 when purchasing tobacco, banning self-service and vending machine sales, and banning free samples. The final rule would also limit the appeal these products have for young people by imposing stringent advertising restrictions on most advertising media. Some of these restrictions include banning billboards within 1000 feet of schools and playgrounds, banning all non-tobacco items identified with a tobacco brand, and sponsorship of events by tobacco companies. The United States District Court for the Middle District of North Carolina (Greensboro Division) upheld the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco products, but delayed implementation of all provisions, pending appeal, except those already in effect for age and ID. The case is currently on appeal in the United States Court of Appeals for the Fourth Circuit.

Resources, Approaches, Processes, Skills, and Technology:

Resources are primarily devoted to inspecting retail facilities and prosecuting those establishments repeatedly found to violate the age and ID restrictions. Resources will also be used to conduct outreach and education programs for retailers and other stakeholders about their responsibilities under the rule, and to coordinate efforts with state and local public health agencies and voluntary health organizations. In addition, resources will be used to develop and implement a regulatory program.

FDA's rule requires that retailers not sell tobacco products to anyone younger than 18 and that they check a photo identification for anyone

FY 1999 Performance Goal Highlights

1. Contract with all 50 states to conduct monthly unannounced compliance checks of retail establishments that sell tobacco.
2. Conduct meetings and a multimedia outreach campaign to educate retailers and other stakeholders about their obligations under the FDA tobacco rules and assist retailers in meeting their new responsibilities.
3. Design and implement a regulatory program for cigarettes and smokeless tobacco products.

younger than 27. FDA will enforce this restriction by commissioning state and local health officials to conduct unannounced purchase attempts using young people under the age of 18. Retailers who do not sell tobacco products to the minor will receive a letter informing them that they are in compliance with the rule. Those who do sell to the minor will receive a letter informing them that they have violated the rule, and that another inspection may occur in the near future. If on the second purchase attempt, the retailer sells to the minor, the Agency will seek to impose a \$250 civil money penalty. Penalties for subsequent violations rise to \$10,000.

FDA will create a database of all retailers who sell tobacco and assign retailers to be inspected and reinspected to each commissioned state. The reports of the inspection will be faxed to FDA who will mail a letter to the retailer and a copy to the state. The database will also be augmented by reports of suspected retailer violations made by citizens using FDA's toll free hotline and FDA's website.

FDA will also work with retailer organizations and other stakeholder organizations to inform them of their responsibility under the rule and to assist them in complying with the rule. Regional meetings and teleconferences will be held as new provisions of the rule come into effect. Materials will also be available on FDA's website and via FDA's toll free hotline. Finally additional materials will be developed as new issues of compliance arise.

FDA will work closely and cooperatively with the Centers for Disease Control and Prevention's (CDC's) Office on Smoking and Health and the Substance Abuse and Mental Health Services Administration (SAMHSA) to conduct surveys to measure compliance with the rule, to monitor buy rates, and to measure success in reducing initiation and use of tobacco by young people. These surveys will be primarily of two types: 1) a national survey of young people to determine among other things, initiation, prevalence, buy rates, and actual or attempted buys; and 2) a national field inspection survey in which a random sample of different types of retail establishments are surveyed for illegal sales. The findings of these surveys would be widely reported and used to determine whether additional measures are needed, and to motivate directed efforts to address documented high-violation-rate segments of the tobacco-distribution system.

The CDC IMPACT program and NCI ASSIST program both involve tobacco control activities at the state and local levels. The state officials participating in the IMPACT and ASSIST programs are potential partners for the implementation of FDA's final rule. This increased effort in the arenas of outreach and enforcement activities, coupled with coordinated efforts by CDC, SAMHSA and other components in the Department of Health and Human Services (DHHS),

will enhance the DHHS's ability to meet its long-term goal of reducing young people's use of tobacco by 50 percent over 7 years. Finally, in FY 1999, FDA will design and, to the fullest extent permitted under any court orders addressing such activities, begin to implement a regulatory program for cigarettes and smokeless tobacco products under the Food, Drug, and Cosmetic Act, including:

1. The beginning of the classification of the product pursuant to Section 513 of the Act;
2. The beginning of the inspection process by reviewing the practices of tobacco companies and the provision of assistance to the industry in coming into compliance with the requirements of the quality system regulations pursuant to 21 CFR, Part 820;
3. The beginning of the appropriate review and analysis of the ingredients and constituents; and
4. Establishment of an evaluation and review procedure for new products.

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TOBACCO PERFORMANCE GOALS

Strategic Goal Area: POSTMARKET ASSURANCE

Cluster: Tobacco

1. *Enter into contracts with all 50 states (depending on their willingness) to conduct an average of 42,000 unannounced compliance checks each month of retail establishments that sell tobacco products. [1]*

Agency Strategies: Maintain inspection visibility. Collaborate with federal and state regulators to reduce health risk. Use third-parties for routine compliance monitoring.

Data Sources: Completed contracts with states.

Baseline Data: Under development. [2]

2. *Conduct meetings and a multimedia campaign, including point-of-purchase, radio, outdoor advertising, and newspapers, to educate retailers and other stakeholders about their obligations under the FDA tobacco rules and the impact of the rules. Distribute at least 100,000 brochures and fact sheets to retailers on request.*

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Internal FDA records.

Baseline Data: Under development. [2]

3. *Design and, to the fullest extent permitted under any court orders addressing such activities, begin to implement a regulatory program for cigarettes and smokeless tobacco products, including:*

- *The beginning of the classification of the product pursuant to Section 513 of the Act.*
- *The beginning of the inspection process by reviewing the practices of tobacco companies and the provision of assistance to the industry in coming into compliance with the requirements of the quality system regulations pursuant to 21 CFR, Part 820.*
- *The beginning of the appropriate review and analysis of the ingredients and constituents, and*
- *Establishment of an evaluation and review procedure for new products.*

Agency Strategies: Develop science-based product and process standards.

Data Sources: Internal FDA records and industry submissions.

Baseline Data: Under development. [2]

1. Achievement of goal assumes that additional personnel can be acquired via contract or other means.
2. Note about performance baselines: Performance baselines will be developed using existing internal tracking data and a newly developed computer tracking system. Data from surveys conducted by the CDC's Office on Smoking and Health and from the Monitoring the Future Project (funded by a grant from the National Institute On Drug Abuse (NIDA)), once the program is fully implemented, will be used to measure rates of initiation and tobacco use by young people. In addition, the DHHS Data Council, which coordinates all health and non-health data collection and analysis activities of DHHS, asked DHHS agencies (e.g., FDA, SAMHSA, and CDC) to review the data requirements which could arise from the potential legislative settlement with the industry. Based upon this charge, a DHHS-wide workgroup was formed to review the data requirements for: youth surveillance; environmental tobacco smoke (ETS) exposure; monitoring social and policy factors; and tobacco product and smoke constituents surveillance. The workgroup will provide the Secretary with recommendations regarding the data needs and appropriate methods for all five areas, including designing surveys to measure baseline and performance goals. These surveys will provide FDA with the appropriate measurement devices for its performance goals

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IMPORTS

STRATEGIC GOAL AREA: POSTMARKET ASSURANCE

Cluster: Imported Products

Cluster Rationale: FDA is responsible for assuring that 50 billion dollars in annual food, drug and devices imports meet regulatory requirements necessary for marketing and consumption within the United States. FDA operates in a dynamic environment characterized by: rapid growth in the volume of import shipments (from 1.5 million in 1990 to more than 3 million in 1997); increasingly complex products; diversity in the technological competence of sources; emerging pathogens and novel public health risks; changing global trade patterns; and evolving approaches to international regulation.

Resources, Approaches, Processes, Skills and Technology: FDA, working independently, would find it very difficult to address these regulatory challenges. FDA inspectors, for example, can physically examine only a small percentage of import entries. Consequently, the Agency has undertaken a combination of strategies which will provide a rigorous, comprehensive assurance of import quality. These strategies are directed toward: enhancing measures within source countries to reduce the likelihood of shipment of violative products to the U.S.; rapidly screening documentation of all entries to identify probable violative products; and promptly assessing potentially violative products at their point of entry.

Preventive Measures Applied At the Source of Production (Goal 1) FDA relies on strategies that increase its confidence in the safety and efficacy of imports at their source of production. This assurance is obtained in a variety of ways. U.S. consumer interests are protected in the process of negotiating bilateral and multinational agreements on specified products and in forums that result in development of acceptable international product standards. These standards may be extended to a larger percentage of imports through the use of third-party certifications, and via agreements that source countries confirm product conformance to these standards. Preventive measures are also achieved through inspection of foreign manufacturers by FDA, primarily for drug and medical device products.

Rapid Access To Safe Products (Goal 2) FDA is relying on an electronic screening system as a key strategy in managing the growing volume and complexity of imports that are entering the U.S. from a widening variety of sources. This system, the Operational and Administrative

FY 1999 Performance Goal Highlights

1. Accept 20% of imports into the U.S. market through evidence of equivalent source-country quality systems, standards or audits.
2. Enhance screening capabilities while ensuring that 55% of entries are released within 15 minutes.
3. Assess potentially violative imports through direct examination of 3% of entries.

System for Import Support (OASIS), allows for quick review of entries, based on mutual agreements with source countries, experience from product violation patterns, and products with a high-risk potential. Electronic access to this history enables FDA to separate products that can be rapidly cleared for entry from those that require physical examination and /or laboratory analysis. OASIS will become an increasingly "smart" system as more comprehensive background information can be accessed, leading to a higher percentage of import entries for which prompt, comprehensive risk assessment decisions can be made. FDA is leveraging its resources in this strategy through partnership with the U.S. Customs Service for both the management of the system and in the development of additional information to facilitate enhanced regulatory decision-making.

FY 1999 will be the first year for which a full year of OASIS operation experience and data will be available to Agency managers to assess the use of and need for resources. The automation of easy product entry decisions for foods has nearly been exhausted. Additional progress in automating entry decisions for either the drug or device programs will depend on the ability to devote resources to build the infrastructure needed to link their data systems into OASIS so that more information can be available on line.

Preventing Violative Products From Entry (Goal 3) FDA must continue to devote a substantial proportion of its import resources to maintain a highly responsive capability for monitoring potentially violative imports. In the past, this vigilance has focused on the containment of such import risks as chemical contaminants in the food supply, pesticide residues in fruits and vegetables, and lead in ceramic dinnerware. Dramatic increases in global trade make FDA's job more challenging than ever because product components and adulterants are available that do not yet conform to FDA's standards. To the extent that preventive measures within source countries prove effective, such risks can be decreased via means that require less direct analysis by FDA officials. However, the FY 1999 environment necessitates that FDA maintain a continuing level of import sampling and examinations to respond to evolving and unexpected import risks.

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IMPORTS PERFORMANCE GOALS

Strategic Goal **POSTMARKET ASSURANCE**
Area:

Cluster: **Imports**

1. *Accept at least 20% of imports into the U.S. market through evidence of equivalent source country quality systems/standards/audits.*

Agency Strategies: Integrate import and international harmonization activities.

Data Sources: Internal management data and U.S. Department of Commerce trade statistics.

Baseline Data: The international trade data used to evaluate the status of this goal are affected by the nature and timing of evolving international agreements and standards. These data will be used to determine the volume of imports that conform with FDA requirements under these agreements and standards.

2. *Enhance import screening capabilities for public health while ensuring that 55% of entries are released within 15 minutes.*

Agency Strategies: Develop science-based product and process standards.

Data Sources: OASIS records.

Baseline Data: FY 1997: approx. 50%

3. *Assess potentially violative imports through direct examination of 3% of entries.*

Agency Strategies: Maintain inspection visibility.

Data Sources: Field Information System.

Baseline Data: FY 1997: approx. 2%.

FY 1996: 3.3%.

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EXTERNAL LEVERAGE

STRATEGIC GOAL AREA: EXTERNAL LEVERAGE

FY 1999 Performance Goal Highlights

1. Establish regulatory partnerships with every state.
2. Conduct 75 industry workshops that result in increased compliance and consumer protection.
3. Correct a majority of problems noted in manufacturing or processing operations via cooperative action.

Cluster: External Leverage

Cluster Rationale: An effective way that FDA can meet its challenge of assuring the safety of regulated products in the marketplace is by developing ways to utilize partners in mutually advantageous endeavors.

Resources, Approaches, Processes, Skills, and Technology:

Through regional and district offices and program centers, ORA will increase the number of Federal-state partnerships that are built on the abilities of partners. Partnership Agreements focus on program responsibilities in such areas as inspections, sample collection, sample analysis, and joint development of shared databases.

In industry workshops, there is exchange of technical and scientific knowledge and information on laws and regulations between FDA and industry professionals. FDA conducts industry workshops on a variety of regulated products in order to increase compliance and consumer protection.

Cooperative actions with industry to obtain compliance are an efficient, effective tool for FDA. The Agency uses the Compliance Achievement Reporting System (CARS) to capture industry compliance to FDA requirements when it occurs prior to a legal action. Activities to accomplish compliance include inspections, meetings held with industry, sending notification of analytical results, issuance of Warning Letters, or import detentions. The Agency plans to coordinate the data in the CARS system with that of the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a new, more flexible and comprehensive Field data system for which implementation begins in FY 1998. This combination of compliance achievement information will better enable the Agency to evaluate its progress toward achieving its strategic goal of postmarket assurance.

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EXTERNAL LEVERAGE PERFORMANCE GOALS

Strategic Goal Area: **EXTERNAL LEVERAGE**

Cluster: **External Leverage**

1. *Expand the system of State Partnership Agreements to comprise at least one per state to increase both quality and efficiency between the Federal, state, and local officials.*

Agency Strategies: Collaborate with Federal and state regulators to reduce health risks.

Data Sources: Office of Regulatory Affairs State-Federal Partnership Agreement Data Base.

Baseline Data: FY 1997: 104 Partnerships established in 43 states.

2. *Publicize and conduct 75 workshops for regulated industry coordinated and/or*

sponsored by the FDA field offices focusing on providing Agency-wide product line training that results in increased compliance and consumer protection.

Agency Strategies: Inform and assist firms to achieve compliance.

Data Sources: Office of Regulatory Affairs - Field Information.

Baseline Data: FY 1998: Baseline being established.

3. *Correct a majority of significant problems identified in manufacturing/processing operations via prompt, cooperative action.*

Agency Strategies: Inform and assist firms to achieve conformance.

Data Sources: This performance goal is intended to reflect a major strategic shift that has occurred in FDA's field operations, from traditional "command and control" regulation toward a collaborative, problem-solving focus. In 1996, FDA initiated a data collection system, the Compliance Achievement Reporting System (CARS), to collect information on instances in which FDA officials obtained compliance through voluntary actions by firms as a result of regularly scheduled inspections, meetings with firms, notification of analysis or import detentions. The data system that captures these successes, CARS, will be coordinated with the new Field Accomplishment and Compliance Tracking System (FACTS) during FY 1999 so that a comprehensive baseline of information on problem types, categories of intervention and problem solutions can be established. This combination of compliance achievement information will enable the Agency to evaluate its progress toward achieving its strategic goal of postmarket assurance through cooperative action.

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Glossary of Acronyms

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| 510(k) | Premarket notification for medical devices substantially equivalent to products already on the market |
| AADA | Abbreviated Antibiotic Drug Application |
| ADAA | Animal Drug Availability Act of 1996 |
| ADE | Adverse Drug Event |
| ADR | Adverse Drug Report |
| AERS | Adverse Events Reporting System |
| AIDS | Acquired Immune Deficiency Syndrome |
| ANDA | Abbreviated New Drug Application |
| ANSI | American National Standards Institute |
| BLA | Biologic License Application |

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| BRFS | Behavioral Risk Factors Survey |
| BRMS | Biologics Regulatory Management System |
| BSE | Bovine Spongiform Encephalopathy (Mad Cow Disease) |
| CARS | Compliance Achievement Reporting System |
| CBER | FDA Center for Biologics Evaluation and Research |
| CDC | Centers for Disease Control and Prevention |
| CDER | FDA Center for Drug Evaluation and Research |
| CDRH | FDA Center for Devices and Radiological Health |
| CFSAN | FDA Center for Food Safety and Applied Nutrition |
| CGMPs | Current Good Manufacturing Practices |
| CJD | Creutzfeldt-Jakob disease |
| COMIS | Center-wide Oracle Management Information System |
| COMSTAT | Compliance Status Information System |
| CRADA | Cooperative Research and Development Agreement |
| CRS | Contamination Response System |
| CVM | FDA Center for Veterinary Medicine |
| DHHS | Department of Health and Human Services |
| DOD | Department of Defense |
| DoL | Department of Labor |
| DRLS | Drug Registration and Listing System |
| DSHEA | Dietary Supplement Health and Education Act |
| EDR | Electronic Document Room |
| EIR | Establishment Inspection Report |
| ELA | Establishment License Application |
| EPA | Environmental Protection Agency |
| ETS | Environmental Tobacco Smoke |
| EU | European Union |
| FACTS | Field Accomplishment and Compliance Tracking System |
| FAO | United Nations Food and Agricultural Organization |
| FAS | USDA Foreign Agriculture Service |
| FDAMA | Food and Drug Administration Modernization Act of 1997 |
| FD&C Act | Federal Food, Drug and Cosmetic Act |
| FPLA | Fair Packaging and Labeling Act |
| FSI | National Food Safety Initiative |
| FTE | Full-time employees |
| FY 1999 | Fiscal Year 1999 (October 1998 - September 1999) |
| GAPs | Good Agricultural Practices |

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| GATT | General Agreement on Tariffs and Trade |
| GPRA | Government Performance and Results Act of 1993 |
| GMPs | Good Manufacturing Practices |
| GRAS | Generally Recognized as Safe food ingredients |
| HACCP | Hazard Analysis Critical Control Points (a quality assurance and inspection technique) |
| ICH | International Conference on Harmonization |
| IDE | Investigational Device Exemption |
| INADA | Investigational New Animal Drug Application |
| IND | Investigational New Drug |
| ISO | International Standards Organization |
| IT | Information technology |
| JIFSAN | Joint Institute for Food Safety and Applied Nutrition |
| LAN | Local Area Network |
| MDR | Medical Device Reporting system |
| MOU | Memorandum of Understanding |
| MQSA | Mammography Quality Standards Act |
| NADA | New Animal Drug Application |
| MRA | Mutual Recognition Agreement |
| NAFTA | North American Free Trade Agreement |
| NASS | National Agricultural Statistics Survey |
| NCTR | FDA National Center for Toxicological Research |
| NDA | New Drug Application |
| NDE/MIS | New Drug Evaluation Management Information System |
| NIDA | National Institute on Drug Abuse |
| NIEHS | National Institute for Environmental Health Sciences |
| NLEA | Nutrition Labeling and Education Act |
| NME | New Molecular Entity |
| NPR | National Performance Review |
| NSE | Not substantially equivalent determination |
| NTP | National Toxicology Program |
| OASIS | Operational and Administrative System for Import Support |
| ORA | FDA Office of Regulatory Affairs |
| OSHA | Occupational Safety and Health Administration |
| OTC | Over-the-counter |
| PAS | FDA Public Affairs Specialist |
| PDUFA | Prescription Drug User Fee Act of 1992 |
| PIMA | Pesticide Management Improvement Act |

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| PLA | Product License Application |
| PMA | Pre-Market Approval (Application to market medical device that requires pre-market approval) |
| PODS | Project-Oriented Data System |
| RCHSA | Radiation Control for Health and Safety Act |
| REGO | Reinventing government initiative |
| RVIS | Residue Violation Information System |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SN/AEMS | Special Nutritionals Adverse Events Monitoring System |
| UMCP | University of Maryland-College Park |
| USDA | United States Department of Agriculture |
| VFD | Veterinary Feed Directive |
| WHO | United Nations World Health Organization |
| WTO | World Trade Organization |