100 Years of Protecting and Promoting Women's Health

PIONEERS IN CONSUMER PROTECTION
1906 - 2006
FDA Centennial
LEADERS IN THE SCIENCE OF PUBLIC HEALTH

Every morning when you wake up and

brush your teeth

put in your contact lenses

microwave your breakfast

take your medicine

feed your pet

select a lipstick

go grocery shopping

get a flu shot or a mammogram....

You have been touched by the
U. S. Food and Drug Administration.

2006

The Food and Drug Administration (FDA) is America's oldest consumer protection agency. Throughout its **100-year** history, the FDA has been working to improve the health of all Americans including some special programs for American women. The FDA's responsibilities have changed dramatically over this time, in response to public tragedies as well as scientific discoveries.

FDA regulates over 1 trillion dollars worth of products, which account for 25 cents of every dollar spent every year by American consumers. As part of its consumer protection role, FDA regulates a wide array of products:

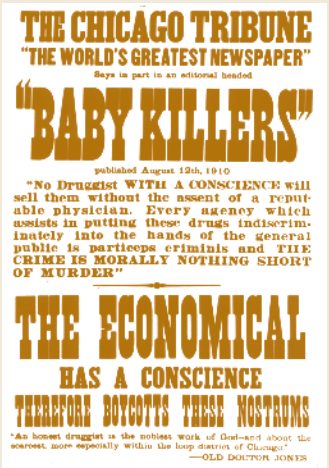
- our food supply (except for meat, and poultry),
- medicines (human and animal),
- medical devices and diagnostic products (such as pregnancy test kits),
- radiation emitting devices (such as microwaves and televisions),
- vaccines, blood and tissue products, and
- cosmetics.

This booklet outlines the FDA's historical and present role as a public health agency. It will also serve as a resource for information about its duties and where to get more information about foods, drugs, medical devices, biological products and cosmetics regulated by FDA.

For more information about the FDA's mission and responsibilities, see our home page: www.fda.gov.

For this brochure, we chose products important to women throughout their lives and for different diseases and conditions. However, only the first of a kind is listed. Please note that mention of a product does not constitute an endorsement.

1906: Fighting Addictive "Medicines"


THE CHICAGO TRIBUNE
"THE WORLD'S GREATEST NEWSPAPER"
Says in part in an editorial headed
"BABY KILLERS"
published August 12th, 1910
"No Druggist WITH A CONSCIENCE will sell them without the assent of a reputable physician. Every agency which assists in putting these drugs indiscriminately into the hands of the general public is particeps criminis and THE CRIME IS MORALLY NOTHING SHORT OF MURDER"
THE ECONOMICAL
HAS A CONSCIENCE
THEREFORE BOYCOTTS THESE NOSTRUMS
*An honest druggist is the noblest work of God—and about the scarcest, more especially within the loop district of Chicago".
—OLD DOCTOR JONES

Problem: Some syrups to calm colicky babies and "tonics" or women contained alcohol, opium, or morphine, addicting many who used them. Worthless, impure and dangerous patent medicines, and foods that were misrepresented or impure were on the market.

Response: Because of these problems, women organized to support the Food and Drugs Act of 1906. To protect the public's health, the law:

- created the first government regulatory agency–known today as the Food and Drug Administration (FDA),
- required dangerous ingredients to be labeled on all drugs, and
- allowed for seizure of illegal foods and drugs.

For more information, go to www.fda.gov and use the search word "history."

1933: Protecting The Health of Women

An exhibit of dangerous food, medicines, medical devices and cosmetics was prepared to illustrate the shortcomings of the 1906 law. First Lady Eleanor Roosevelt took this exhibit to the White House and appealed to America's women to campaign for stronger protections for consumers.

"America's Chamber of Horrors" Exhibit

The famous exhibit included the following harmful products:

- *a "womb supporter" (also used as a contraceptive) that could puncture the uterus if inserted the wrong way.*
- *a weight-loss drug that caused death.*
- *a hair remover that caused baldness, even if not used on the head.*
- *lotions and creams that could cause mercury poisoning, and hair dyes that could cause lead poisoning.*
- *an eyelash dye that blinded women.*

1937: Targeting Unsafe and Unproven Products

Problem: A company manufacturing one of the first wonder drugs against infection (sulfanilamide) dissolved it in a poisonous liquid. Before the problem was discovered, 107 people, mostly children, died. Until this time, there were no government regulations requiring that drugs be tested and found safe before going on the market.

Response: As a result, Congress passed the federal Food, Drug, and Cosmetic Act of 1938. The new law:

- required manufacturers to prove that a new drug was safe for its intended use when used under the conditions of the label, to include a full list of ingredients for a drug, and to show manufacturing was satisfactory.
- allowed regulation for the first time of cosmetics and medical devices, in addition to foods, drugs, and biological products; and
- provided for food standards and detailed package labeling.

For more information, go to www.fda.gov and use the search term "FD&C Act."

Nutrition Facts

Serving Size ½ cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	20%
Saturated Fat 5g	25%
Cholesterol 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	11%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	

Vitamin A 4% •	Vitamin C 2%
Calcium 15% •	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Key FDA Food Milestones

1940s: Iron added to breads, cereals and flour to prevent iron-deficiency anemia.

1980: Congress passed the Infant Formula Act after low-chloride formula caused harm in infants.

1994: New food labels required to provide clearly readable information on fat, cholesterol, dietary fiber and other key nutrients.

1997: Food Safety Initiative took measures to reduce food contamination, such as with E. coli.

1998: Folic acid required to be added to grain products to prevent neural tube defects in infants.

2000: Health warnings required on egg cartons to prevent Salmonella illness.

2001: Advisory issued to women who might become pregnant, pregnant women, nursing mothers, and young children to limit intake of certain fish and, shellfish to reduce mercury risk.

Key FDA Food Milestones, cont.

2001: Advisory issued to reduce risk of "listeria" from ready-to-eat foods.

2003: FDA required manufacturers to list trans fat on the Nutrition Facts label on foods and some dietary supplements.

1945: From Flu Shots to New Technologies

In 1945, the Army developed a flu vaccine that cut the rate of infection by 75%. By 1946, it became available to civilians. Many women remembered family stories about the 1918 flu pandemic which had killed 675,000 people–a loss reported to have affected someone from every family in America.

Key FDA Vaccine and Biologics Decisions

1945: Influenza (flu) vaccine.

1949-63: Diphtheria, Tetanus, Pertussis (DTP); mumps and measles vaccines.

1955-63: Polio vaccines.

1971: German measles (rubella) vaccine.

1977: Pneumonia vaccine.

1981: Hepatitis B vaccine.

1985: Hemophilus vaccine.

1996: Varicella (chicken pox) vaccine Pertussis vaccine -- New and improved with fewer side effects.

1998: Lyme disease vaccine.

2004: Human donor tissues for pregnancy must be tested for diseases such as HIV and hepatitis.

1960: Beginning a New Era of Birth Control

1960: FDA approved the first oral contraceptive, commonly called "The Pill."

1970: FDA initiated the first package insert written for consumers to explain to women the benefits and potential risks of oral contraceptives.

2001: Approved first transdermal (skin) patch, and first hormonal vaginal ring for birth control.

For more information, go to www.fda.gov and search the words "birth control guide."

1961: Spurring Drug Reforms to Prevent Birth Defects

Problem: In Europe, approximately 10,000 infants born with deformed arms and legs were linked to thalidomide, a drug their mothers had taken during pregnancy

Response: Due to the efforts of a woman scientist, and drug reviewer Frances Kelsey, (M.D./ Ph.D.), FDA did not approve the drug for use in America. Worldwide alarm led to stronger drug laws here and in many other countries. In the U.S., the 1962 Kefauver-Harris Amendments to the federal Food, Drug, and Cosmetic Act of 1938:

- Required a drug to be tested in animals before being tested on people;
- Made investigators responsible for supervising drugs under study;
- Required manufacturers to inform participants if a drug was being used for investigational purposes and obtain their consent;
- Required that drugs be shown to work (be effective) before marketing;
- Required manufacturers to report unexpected harm (adverse events); and
- Gave FDA authority to regulate advertising of prescription drugs.

For more information, go to www.fda.gov and search the word "thalidomide."

1968: Protecting Babies

To prevent complications in Rh negative mothers, FDA licensed Rh immunoglobulins.

1971: Issuing Warnings that Products are Unsafe for Pregnant Women

Problem: Since 1948, diethylstilbestrol (DES) had been prescribed (without the supporting scientific data) to thousands of pregnant women believed to need more estrogen to maintain their pregnancies. Exposed in the womb to DES, the daughters developed a rare form of vaginal cancer.

Response: FDA changed the labeling on this hormone to warn women against taking this drug during pregnancy.

For more information, go to www.fda.gov and search the words "promoting healthy babies."

Women in Clinical Trials

1977: After the tragedies caused by the use of thalidomide and DES in pregnant women, FDA guidance recommended against including women of child bearing potential in the early phases of drug testing except for life-threatening illnesses.

1993: FDA issued a guideline calling for the study of drugs in both women and men in the evaluation of medicines. This guideline allowed the restriction on women of child bearing potential to be lifted and allowed them in early phase clinical trials. The 1993 guideline emphasized the need for representation of both women and men in clinical trials to allow detection of clinically significant gender/sex differences.

1998: FDA published its final rule requiring New Drug Applications to examine and include data on safety and effectiveness by gender/sex, age and race.

2002: A Congressional mandate called for an "agency-wide database focused on women's health activities." OWH created the Demographic Information and Date Repository (DIDR), an electronic way to review clinical studies, enhance product labeling, identify gaps, and coordinate data collection.

Note: It is important to include women in clinical trials to determine how women and men respond to medicines. To be sure that medical products are safe and effective for all those who use them, these products should be tested in both women and men, and the data examined for differences in both favorable and unfavorable responses.

1976: Strengthening Authority over Medical Devices

Problem: Approximately 2 million women had a contraceptive device, the Dalkon Shield IUD, inserted in their uteruses. Due to problems with this device, many women were seriously injured.

Response: In reacting to this tragedy, Congress passed the 1976 Medical Devices Amendments, which strengthened FDA's authority to oversee medical devices.

Key FDA Device Actions

1978: Approved first over-the-counter pregnancy test kit.

1979: Approved x-ray machine to measure bone mineral density.

1985: Permitted makers of latex condoms to add information to their labeling that their products protect against sexually transmitted diseases, including AIDS.

1991-2: Required manufacturers of silicone breast implants to submit data showing safety and effectiveness or have their product taken off the market. When adequate data was not demonstrated, FDA restricted the use of silicone gel-filled breast implants to those women with a medical need.

1994: Approved first blood test to measure a tumor marker that can help determine if breast cancer has recurred.

1998: Approved computerized devices to help analyze mammograms and pap smears.

2000: Approved test for HER2 protein in breast cancer tumors to select patients most likely to respond to treatment with Herceptin.

2000: Approved test for human papillomavirus (HPV) in cellular DNA before conclusive changes to the cervical cells are present.

2004: Approved magnetic resonance image (MRI) device which uses ultrasound to destroy uterine fibroids without surgery.

1980: Making Tampon Use Safer

Problem: In 1980, there were 814 confirmed cases of menstrual related Toxic Shock Syndrome (TSS) and 38 deaths from the disease.

Response: FDA began requiring all tampon packages to include package inserts educating women about the risk of TSS and how to prevent it. In 1997, there were only five confirmed menstrually-related TSS cases and no deaths. The tampon package inserts with TSS information continue to be used today.

For more information, go to www.fda.gov and search words "toxic shock."

1982: Eliminating Lethal Tampering

Problem: Seven people died from Tylenol capsules intentionally contaminated with cyanide.

Response: FDA issued regulations requiring tamper-resistant packaging for over-the-counter drugs.

1992: Improving Mammograms

Problem: Women and their doctors testified before Congress about problems with mammography, including untrained personnel, old machines, and failure to communicate test results.

Response: Congress passed the Mammography Quality Standards Act (MQSA), which imposed standards for mammography personnel, equipment, record keeping, and regular FDA inspections of mammography facilities. FDA also started an information ervice to help women find a quality mammography facility through the National Cancer Institute toll-free phone number (1-800-4-CANCER).

1998: Approved computerized devices to help analyze mammograms and pap smears.

2000: Approved first digital mammography system.

For more information, including how to find a certified mammography center, go to www.fda.gov/CDRH/MAMMOGRAPHY/certified.html

Key FDA Drug Actions

1942: First product (conjugated estrogens) marketed for treatment of menopausal symptoms.

1967: First drug approved for induction of ovulation to promote fertility.

1974: Sequential oral contraceptives that increased the risk of endometrial cancer were withdrawn.

1977: New types of drug that block estrogen receptor approved for treatment of patients with advanced breast cancer.

Key FDA Drug Actions, cont.

1987: First of a new class of drugs (selective serotonin reuptake inhibitors [SSRIs]) approved for depression.

1988: Birth control pills containing more than 50 micrograms of estrogen with drawn from the market because of association with higher risk for rare, but fatal thromboembolisms.

1994: Information on the prevention of transmission of the HIV virus from HIV+ pregnant women to their fetuses between 14 and 34 weeks included in the label of an antiretroviral drug.

1996: Announced a new initiative to accelerate approval of cancer drugs by recognizing that tumor shrinkage is often an early indicator of effectiveness.

1997: Additional drugs approved for prevention and treatment of osteoporosis.

1998: FDA issued warnings about the dangers of mixing alcohol with pain relievers.

2000: First drug approved for pregnancy termination without the use of surgery.

2002: First approved drug for treating osteoporosis that stimulates new bone formation.

2003: First of a new class of drugs approved to treat moderate to severe Alzheimer's disease.

2006: First inhaled insulin approved for treatment of type 1 or type 2 diabetes.

1994: Advocating for Women: Office of Women's Health

FDA created the Office of Women's Health (OWH), beginning a new chapter in this agency's commitment to women's health. Serving as a champion for women's health both inside and outside the agency, OWH safeguards the health and well being of American women in a variety of ways by:

- Providing scientific and policy input on many of today's leading women's health issues;
- Funding research and education/outreach programs on pressing women's conditions and diseases;
- Encouraging industry to include women in their clinical trials; and
- Communicating important public health messages to and from the public.

For more information, go to www.fda.gov/womens

OWH Outreach: Providing Essential Information

Problem: Data indicate that between family, work, and community responsibilities, women are often so busy taking care of others that they overlook their own health needs.

Response: OWH launched the ***"Take Time to Care"*** (TTTC) outreach initiative in 1998. Over the years, TTTC has become a multi-faceted campaign that focuses on the dissemination of health education materials through outreach activities and collaborative partnerships. OWH has also developed dozens of fact sheets and publications on topics including: heart disease, stroke, Lasik eye surgery, mammography, food safety, contraception, depression, HIV, osteoporosis, tattoos, Botox, menopause and hormones.

Since 1999, OWH has reached over ***26 million*** consumers with its literature. OWH publications also are distributed through Internal Revenue Service and Congressional mailings. In 2005, OWH materials received the highest response of any mailing to Congress. An article in the nationally syndicated advice column ***Dear Abby*** promoting the Women's Health Education Kit sparked an overwhelming number of consumer requests for more than ***two million*** publications.

1998: Speeding up the approval process

Congress amended the Federal Food, Drug and Cosmetic Act by passing the Food and Drug Administration Modernization Act (FDAMA). With the passage of FDAMA, Congress enhanced the FDA's mission to meet the challenges of the 21st century, such as establishing mechanisms to decrease the time FDA takes to review and approve applications. This Act also called for FDA to receive input from its stakeholders.

1998-1999: Conferring with stakeholders

FDA held meetings across the country to exchange information with stakeholders on issues related to it's regulation drugs, biologics, medical devices, veterinary medicines, foods, inspections of manufacturers, and FDAMA.

2004: Critical Path

FDA called for a new focus on modernizing the tools that researchers and product developers use to assess the safety and effectiveness of potential new products and to mass-produce high-quality therapies. New scientific and technical tools–like laboratory tests, computer models based on past experience, and animal studies–

will improve predictability and efficiency of products in development. These new tools will help create safe products that benefit patients.

More Progress to Come: Personalized Medicine

We now have technologies that allow us to study each person in greater detail than ever before. We can understand the configuration of each individual's genes. We can understand how individuals react to the course of a disease and to a treatment. In the future, the public will see new tests and new therapies that are personalized to specific conditions and that can improve health while minimizing risk of serious side effects.

U.S. Women	1900's	2000's
Age at death	48 years	80 years
Primaty causes of death	TB and child birth	Heart disease
Average #children	8	1.86
Infant mortality rates	124-158 per 1,000	7 per 1,000
Number in workforce	Not counted	59%
Eligible Voters	0%	51%

This information reflects FDA's current analysis of data available to FDA concerning these products. The information on this booklet may also be found at www.fda.gov/womens.

To report any unexpected adverse or serious events associated with the use of a medication, please contact the FDA MedWatch program at 1-800-FDA-1088 or www.fda.gov/safety/medwatch/default.htm.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