development, manufacture and sale of products for the treatment of Factor VIII inhibitors in the United States; and in the market for the research, development, manufacture and sale of fibrin sealant in the United States.

The proposed Order would remedy the alleged violations. In the market for the research, development, manufacture and sale of treatments for Factor VIII inhibitors in the United States, the proposed Order requires Baxter to divest its Autoplex product to a Commission approved buyer within four months. Baxter's Autoplex and Immuno's FEIBA are the only FDA-approved activated prothrombin complex concentrates for the treatment of patients with hemophilia A who have developed an immune system response to their therapy, known as ''inhibitors''. Autoplex and FEIBA act to overcome these patients' inhibitors so that they can be treated effectively. The acquisition would eliminate the substantial competition between Autoplex and FEIBA. The proposed Consent Agreement would remedy the loss of competition by requiring Baxter to divest Autoplex to a Commission-approved buyer within four months of the date Baxter signed the Consent Agreement.

In Europe and Japan, fibrin sealants are used to control bleeding and promote wound healing in a wide variety of surgical procedures, and to treat burn and trauma victims. Baxter and Immuno are two of only a few companies developing fibrin sealant for sale in the United States, and are likely to be two of the first companies to receive FDA approval to do so. The United States market for an FDA-approved fibrin sealants could be as large as $400 million per year. The acquisition would eliminate the significant on-going competition between Baxter and Immuno in the research and development, as well as future competition in the manufacture and sale, of fibrin sealant in the United States. The proposed Order remedies this loss of competition by requiring Baxter to license Immuno's product in development to a Commission-approved licensee within four months of the date Baxter signed the Consent Agreement.

The Order also requires Baxter to provide to the Commission a report of compliance with the divestiture and licensing provisions of the Order within sixty (60) days following the date the Order becomes final, and every ninety (90) days thereafter until Baxter has completed the divestiture and licensing. The Order also requires Baxter to notify the Commission at least thirty (30) days prior to any change in the structure of Baxter resulting in the emergence of a successor.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Benjamin I. Berman,

*Acting Secretary.*

[FR Doc. 97–4 Filed 1–2–97; 8:45 am]

BILLING CODE 6750–01–P

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**[File No. 961–0055]**

## Ciba-Geigy Limited, et al.; Analysis to Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would permit, among other things, the $63 billion merger of Ciba-Geigy Limited and Sandoz Ltd., two leading commercial developers of gene therapy products, so long as the companies carry out the divestiture, licensing and certain other requirements. If the divestiture is not completed on time, the consent agreement would permit the Commission to appoint a trustee to complete the transaction.

**DATES:** Comments must be received on or before March 4, 1997.

**ADDRESSES:** Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580.

**FOR FURTHER INFORMATION CONTACT:** William Baer or George Cary, FTC/H–374, Washington, D.C. 20580. (202) 326–2932 or 326–3741.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home page, on the World Wide Web, at ''http://www.ftc.gov/os/actions/htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

### Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an agreement containing a proposed Consent Order (''Order'') to resolve anticompetitive concerns raised by the proposed merger of Ciba-Geigy Limited (''Ciba'') and Sandoz Ltd. (''Sandoz'') into a new entity, Novartis AG (''Novartis''). The agreement is between the Commission and Ciba, Sandoz, and Chiron Corporation (''Chiron''). Ciba, which owned 46.5% of Chiron's voting stock as of September 30, 1996, participates in the field of gene therapy through Chiron. Under the proposed Order, the companies have agreed to license certain Sandoz and Chiron gene therapy technologies, to divest Sandoz' corn herbicide business, and to divest Sandoz' United States and Canadian flea control business. In addition, the parties have entered into an Agreement to Hold Separate Sandoz's agricultural chemicals business, including herbicides and other pesticides, and Sandoz's flea control business until the required divestitures have been accomplished.

The proposed Order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will review the agreement and the comments received and will decide whether it should withdraw from the government or make final the agreement's proposed Order.

On March 6, 1996, Ciba and Sandoz signed a merger agreement providing that both companies will merge to form Novartis AG (''Novartis''). The total value of the stock involved in the transaction is in excess of $63 billion. The merged entity, Novartis, will control worldwide assets valued at approximately $80 billion.

The proposed complaint alleges that the merger violates Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by lessening competition or tending to create a

monopoly in markets involving three general areas: (1) gene therapy research and development; (2) corn herbicides; and (3) flea control products. According to the complaint, the merger will increase the level of concentration and increase barriers to entry in each of the relevant markets and eliminate Ciba and Sandoz as substantial, independent competitors both for currently marketed products as well as products that are under development.

According to the proposed complaint, entry into the relevant markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract anticompetitive effects of the merger. Regulations by the Food and Drug Administration (''FDA'') covering gene therapy products and systemic flea control products, and by the Environmental Protection Agency (''EPA'') covering corn herbicides and externally applied flea control products, create long lead times for the introduction of new products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry.

*Gene Therapy Research and Development*

The proposed complaint alleges that therapy technology and the research and development of gene therapies constitute relevant markets in which to analyze the effects of the proposed merger. The proposed complaint also alleges that there are four specific gene therapy closet to market use retroviral vectors, the delivery vehicle for genes, to place an HSV-tk gene into the cancerous cells and are anticipated to have sales exceeding $600 million by 2002. HSV-tk gene therapy is also expected to be used to treat graft versus host disease, an acute, chronic and sometimes fatal complication occurring in a significant percentage of all bone marrow transplantations. Gene therapy treatments for hemophilia A are likely to be used prophylactically for many sufferers; in cases of trauma, gene therapy products would likely be used in combination with recombinant and purified Factor VIII proteins. Cancer patients could benefit significantly from gene therapy for chemoresistance by providing protection to patients' blood systems and allowing higher, more effective doses of cancer chemotherapy to be administered. If chemoresistance gene therapy research is successful, sales are projected to exceed $1 billion by 2004.

The complaint alleges that each of the gene therapy markets is highly concentrated and that Ciba/Chiron and Sandoz are two of only a few entities capable of commercially developing a broad range of gene therapy products. Ciba/Chiron and Sandoz control crucial inputs into the development of gene therapy products and the merger creates an unmatchable portfolio of intellectual property assets that are necessary to commercialize gene therapy products. In addition, they both posses the technological, manufacturing, clinical, and regulatory expertise and manufacturing capability to commercially develop gene therapy products. A substantial number of other companies are able to conduct gene therapy research. Without licenses to crucial intellectual property held by Ciba/Chiron and Sandoz, however, these other researchers would not be likely to continue development. The critical intellectual property rights for gene therapy held by Ciba/Chiron and Sandoz include a broad patent covering all ex vivo approaches product markets. These are the markets for the research, development, manufacture and sale of: (1) herpes simplex virus-thymidine kinase (''HSV-tk'') gene therapy for the treatment of cancer; (2) HSV-tk gene therapy for the treatment of graft versus host disease; (3) gene therapy for the treatment of hemophilia A; and (4) chemoresistance gene therapy. Sandoz and Ciba/Chiron are two of only a very small number of entities capable of commercially developing gene therapy products. They posses the intellectual property, the technological, manufacturing, clinical, and regulatory expertise, and the manufacturing assets to commercially develop gene therapy products.

Gene therapy involves treating diseases or medical conditions by modifying genes and then inserting the modified genes into a patient's cells. Patients' genes may be altered using one of two broad approaches: ex vivo, outside the body, for subsequent administration into the patient; or in vivo, inside the body, by gene therapy products that are given directly to the patients. Gene therapy research today targets fatal or disabling diseases such as cancer for which there are no current effective treatments and for which no drugs are in advanced development.

While no gene therapy product has yet been approved by the FDA for commercial sale, gene therapy treatments now in clinical trials offer patients the prospect of significant medical improvements or cures for diseases, particularly in oncology, transplantation and central nervous system diseases. Gene therapy may be useful in treating a wide array of diseases and conditions. Sales of all gene therapy products are projected to reach up to $45 billion by 2010.

The first regulatory approvals for commercial sales of gene therapy products, expected by the year 2000, will most likely be in the area of cancer treatment of brain tumors. Gene therapy offers brain cancer patients their first hope of a real cure. The brain cancer gene therapy products used in gene therapy and the use of cytokines, a protein necessary for many ex vivo gene therapy applications that is used to increase the number of cells taken from a patient. The parties also have vital intellectual property rights in retroviral vectors, the only delivery vehicle for gene therapy that has been proven safe and relatively effective.

The complaint alleges that only two companies, Ciba/Chiron and Sandoz, are capable of commercially developing HSV-tk gene therapy products with retroviral vectors and are either in clinical development or near clinical development to treat cancer and to treat graft versus host disease. Similarly, these two companies are the most advanced of all companies capable of commercially developing viral vectors using the Factor VIII gene for the treatment of hemophilia A and using the MDR–1 gene and the MRP gene for the treatment of chemoresistance. In each instance, Ciba/Chiron and Sandoz are either in clinical development or near clinical development for the treatment of these diseases, are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how. For example, with respect to the HSV-tk gene therapy products, both Ciba/Chiron and Sandoz control intellectual property portfolios sufficient to make it likely that they could market HSV-tk gene therapy products in competition with one another. The merger would eliminate that competition, and because of the parties' patent portfolios, it is extremely unlikely that any other firm would be able to enter to replace that lost competition.

The complaint alleges that entry into the gene therapy markets requires lengthy FDA approved clinical trials, data collection and analysis, and expenditures of significant resources over may years. No company may reach advanced stages of development in the relevant gene therapy markets without: (1) clinical gene therapy expertise; (2) scientific research that requires years to complete; (3) patent rights to all the necessary proprietary inputs into the gene therapy product sufficient to provide the company with reasonable

assurances of freedom to operate; and (4) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs may include genes, vectors and vector manufacturing technology, and cytokines.

Ciba/Chiron and Sandoz each possess virtually all of the gene therapy intellectual property needed to ensure their ability to independently perform gene therapy development. Through the merger, the companies' alternative competing gene therapy technologies will be combined, reducing innovation competition. That combination changes the competitive incentives of the merged entity. It will likely lead to a reduction in development of gene therapy products, as the parties combine their research and development pipelines and eliminate or slow down their parallel development projects.

In addition, Novartis, the merged firm, will have a disincentive to license intellectual property rights to or collaborate with other companies as compared to the pre-merger incentives of the independent competitors, Ciba/Chiron and Sandoz. Although Ciba/Chiron and Sandoz had substantial individual intellectual property portfolios pre-merger, they had the incentive and did act as rival centers from which others could obtain needed intellectual property rights. Ciba/Chiron and Sandoz would grant limited intellectual property rights to other developers and researchers in return for receiving marketing or other valuable rights back from them. Consequently, as the complaint alleges, the merger may heighten barriers to entry by resulting in one entity holding so extensive a portfolio of patents and patent applications, of uncertain breadth and validity, as to diminish its incentives to license, thus impeding the ability of other gene therapy researchers and developers to continue developing their products.

To remedy the alleged competitive harm, the proposed Order provides for a set of patent licenses to allow other companies to replace the competition otherwise lost due to the merger. The Commission believes that licensing, rather than divestiture of assets, is sufficient because access to certain key intellectual property rights held by the merged firm is a crucial component of successful commercialization of many potential gene therapy products. Competitors already have (to varying degrees) the hard assets, *e.g.*, production facilities, researchers and scientists, needed to compete. Rivals and other scientists confirm that licensing would enable them to develop gene therapy products and replace the competition lost due to the merger. Further, an asset divestiture might create substantial disruption in the parties' research and development efforts. In this case, therefore, a licensing remedy appears to be the preferred approach to restoring the competition lost by the merger.

The proposed Order includes the following remedy provisions. First, in the research, development, manufacture, and sale of gene therapy, the proposed Order would require Sandoz and Chiron to provide to all gene therapy researchers and developers non-exclusive licenses or sublicenses to certain proprietary and patented technologies essential for the competitive development and commercialization of gene therapy products. In the United States, Chiron owns the rights to commercialize cytokine Interleukin 2 (''IL–2''), and Sandoz has exclusive rights to the Anderson *ex vivo* patent, and claims arising there-under, and owns the rights to cytokines Interleukin 3 (''IL–3'') and Interleukin 6 (''IL–6''). Within thirty (30 days of the date the Order becomes final, the companies are required to grant to other gene therapy researchers non-exclusive licenses to each of these essential gene therapy technologies. In addition, each licensee must be given access to drug master files, the data filed with the FDA establishing the safety and purity of these cytokines. These licensing arrangements will remedy the reduction in competition in research and development of gene therapy caused by the merger.

As detailed in the Order, the IL–2, IL–3 and IL–6 cytokines and the Anderson *ex vivo* patent licenses include a right to a royalty payment at low rates (based upon net sales with no minimum amount). In the past, the Commission has had concerns with royalty payments in connection with licenses that are meant to restore competition eliminated by a merger. This is because continuing entanglements between the divesting company and the acquirer might provide opportunities for information exchange between competitors and interfere with their economic incentives to compete vigorously. These risks are relatively slight under the terms of the proposed Order, particularly because of the low royalties and potential number of non-exclusive licenses to the industry required under the proposed Order. In addition, to minimize further the financial relationships and the exchange of competitively sensitive information among Novartis, Chiron and potential competitor-licensees, an independent auditor will be appointed to collect and aggregate the royalty payments. Sandoz, Ciba, Chiron, and Novartis will be prohibited from gaining access to this confidential sales information. Each license will also include a binding arbitration clause to resolve disputes regarding the royalties or any other terms, a provision that further insulates Sandoz, Ciba, Chiron, and Novartis from interactions with the potential licensees.

Second, the proposed Order provides for further remedies regarding the anticompetitive harm alleged with respect to the HSV-tk product markets. Both Sandoz and Ciba/Chiron are developing HSV-tk gene therapies for cancer and graft versus host disease. After the merger, Ciba/Chiron and Sandoz would control dominating intellectual property portfolios for HSV-tk gene therapy. The proposed Order restores the pe-merger incentives for research, development, manufacture and sale of HSV-tk gene therapy products for cancer and graft versus host disease by requiring licensing of the Sandoz' and Chiron's worldwide HSV-tk patent rights, including rights relating to vectors. By September 1, 1997, Sandoz and Chiron each are required to grant a non-exclusive license to Rhône-Poulenc Rorer (''RPR''), with whom Ciba, Sandoz and Chiron have entered into a letter of intent for this purpose. If the agreement between RPR and Ciba, Sandoz, and Chiron were to fall through, Ciba, Sandoz and Chiron would be required to license these assets to another licensee who has received Commission approval by September 1, 1997. Under the terms of the proposed Order, the license granted to RPR, or an alternative licensee, must include the right to sublicense in fields that are not developed by RPR or the licensee, as well as a technology transfer from Sandoz of necessary HSV-tk know-how, including know-how relating to vectors, within one year of execution of the license.

Third, to ensure the continued research, development, manufacture and sale of Factor VIII gene therapy products for the treatment of hemophilia A, the proposed Order requires that by September 1, 1997, Sandoz shall either: (1) convert its exclusive license for the use in gene therapy of the partial Factor VIII gene to a non-exclusive license; or (2) grant to RPR a sublicense to those gene therapy Factor VIII rights. At the option of the sublicensee, Sandoz may be required to provide technical information and know-how relating to Factor VIII gene therapy products.

Finally, to ensure the continued research, development, manufacture and sale of chemoresistance gene

therapy products in the United States, the proposed Order requires that neither Ciba, Chiron, Sandoz nor Novartis shall acquire exclusive rights in intellectual property and technology related to the MDR–1 and/or MRP genes. With exclusive rights to the genes necessary for this treatment area, both parties would have potentially dominating intellectual property rights for the use of the MDR–1 or MRP chemoresistance genes in gene therapy. The merger combines the parties' two competing chemoresistance gene therapy programs and potentially concentrates the important intellectual property rights for these genes. Thus, the proposed restriction on exclusive licensing of the MDR–1 and MRP genes will ensure access to the chemoresistance genes to at least one other competing company.

The proposed Order also provides for the appointment of a trustee if Novartis and/or Chiron fail to grant any of these licenses within the appropriate time period. In that event, the trustee is authorized to divest either Sandoz' or Chiron's HSV-tk businesses in their entirety.

*Corn Herbicides*

According to the Commission's proposed complaint, the merger of Ciba and Sandoz into Novartis, absent relief, would have adverse effects on various markets for corn herbicide. United States sales of corn herbicides—chemical products designed to kill or control weeds that interfere with corn production—totaled $1.4 billion in 1995. According to the proposed complaint, the markets for corn herbicide are distinguished by the types of weeds—broadleaf or grass—against which the herbicide is chemically effective as well as by the stage of growth of the corn crop or weed—pre-emergent or post-emergent—at which the herbicide is safe for us on the corn crop and chemically effective against the weeds to be controlled.

The Commission's proposed complaint alleges that Ciba's metolachlor herbicides, sold under the brands Dual® and Bicep®, are the leading corn herbicides for pre-emergent control of grasses. The complaint alleges that Sandoz' recently introduced dimenthenamid grass herbicides, sold under the brands Frontier® and Guardsman®, are gaining share against Ciba's metolachlor grass herbicides.

The complaint also alleges that Sandoz' dicamba herbicides, sold under the brands Banvel®, Marksman®, and Clarity®, are the leading corn herbicides for post-emergent control of broadleaf weeds. According to the complaint Ciba's recently introduced sulfonyl urea broadleaf herbicide, sold under the bran Exceed®, is rapidly gaining share against Sandoz' dicamba broadleaf herbicides, and Ciba and Sandoz recognize that current users of Sandoz' dicamba herbicides are the principal target for expected market share gain by Ciba's Exceed® herbicide. Ciba is also the dominant supplier of atrazine, a broadleaf weed control product that is widely used as a component in premixed herbicide formulations sold by Ciba, Sandoz and their competitors.

According to the complaint, each of the corn herbicide markets is highly concentrated, as measured by the Herfindahl-Hirschman Index (''HHI'') and other measures of concentration. Ciba accounts for over 35 percent of corn herbicide sales in the United States and over 40 percent of treated acres, while Sandoz has approximately a 10 percent share by either measure. Further, the complaint alleges that the proposed merger would increase concentration, as measured by the HHI, by approximately 700 points for dollar sales, and by approximately 1000 points for treated acres, to approximately 3000 for sales and approximately 3300 for treated acres.

In the market for pre-emergent treatment of corn acres for grasses, the complaint alleges that Ciba products accounted for over 40 percent and that Sandoz accounted for approximately 3 percent in 1995. The proposed merger would increase concentration in that market, as measured by the HHI, by aprpoximately 300 points to approximately 3400. In addition, in the market for post-emergent treatment of corn acres for broadleaf weeds, the complaint alleges that Sandoz products accounted for over 30 percent and that Ciba's Exceed® brand accounted for approximately 5 percent in 1995. Combining Exceed® and other Ciba products with Sandoz' products, the proposed merger would increase concentration in that market, as measured by the HHI, by approximately 1900 points to over 4000.

The complaint alleges that entry into the corn herbicide markets requires over a decade for chemical synthesis; laboratory and greenhouse testing; formulation; process development; pilot production; pilot trials; field trials; testing for acute, subchronic and chronic toxicity, possible carcinogenic and mutagenic effects and effects on prenatal deformation; environmental toxicology testing; measurement of plant, animal, soil, water and air residues and testing of degradation of plant, animal, soil, and water environment; data collection; product registration and EPA review; construction of production facilities; and use optimization. Further, according to the complaint, once a product is introduced to the market, several years are often required to gain customer acceptance through demonstrated safety, performance and reliability, over a variety of weather conditions.

Additionally, the complaint alleges that, despite the expiration of United States patents on dicamba and metolachlor, post-patent strategies pursued by Ciba and Sandoz, including product reformulation, distribution agreements, purchase and supply contracts with manufacturers, and joint product development agreements, have limited entry of generic competition to Ciba's leading pre-emergent grass herbicides and Sandoz' leading post-emergent broadleaf herbicides.

Further, according to the complaint, supply agreements, joint product development agreements, and joint marketing agreements among producers of corn herbicide increase coordinated interaction and the recognition of mutual interdependence among competitors in each of the relevant markets for corn herbicide.

The complaint further alleges that the proposed merger of Ciba and Sandoz would eliminate Ciba and Sandoz as substantial, independent competitors; eliminate actual, direct, and substantial competition between Ciba and Sandoz, including the reduction in, delay of or redirection of research and development projects; eliminate the potential for increased actual, direct and substantial price competition and cause consumers to pay higher prices for corn herbicides; increase barriers to entry; increase the level of concentration in the corn herbicide markets; increase the merged firm's ability unilaterally to exercise market power in the market for corn herbicide for post-emergent control of broadleaf weeds by combining the two closest substitutes in the market; and increase the likelihood and degree of coordinated interaction between or among competitors in the market for corn herbicide for pre-emergent control of grasses.

The Order accepted for public comment contains provisions that would require Sandoz to divest its corn herbicide business, including Sandoz' dicamba and dimethenamid plants in Beaumont, Texas, and United States and Canadian assets to BASF Aktiengesellschaft (''BASF''), no later than ten days after the Order becomes final, pursuant to an agreement between Sandoz and BASF for approximately $780 million. If, through no fault of Sandoz, BASF fails to acquire the

business, the Order requires Sandoz to divest its corn herbicide business, within sixty days after the Order becomes final, to an alternative acquirer approved by the Commission and in a manner that receives the approval of the Commission, and to divest such additional ancillary assets and businesses and effect such arrangements as are necessary to assure the marketability, independence, viability and competiveness of the divested business. The Order further provides for appointment of a trustee to divest Sandoz' agricultural chemicals business, including herbicides and other pesticides, in the event Sandoz is unable to complete the required corn herbicide divestiture within the specified period.

*Flea Control Products*

According to the proposed complaint, the proposed merger will have anticompetitive effects in the market for the research, development, manufacture and sale of flea control products in the United States. Flea control products are chemical products designed to treat and prevent flea infestation in cats and dogs. They are sold in various forms, including pills, collars, shampoos, sprays, and foggers and are sold through various channels of distribution: veterinarians, pet specialty stores, lawn and garden centers, mass merchandisers, and grocery stores. The complaint alleges that there are no economic substitutes for flea control products for the treatment and prevention of flea infestation in cats and dogs.

The complaint further alleges that the flea control products market is a very highly concentrated market that had sales in the U.S. of approximately $400 million in 1995. Ciba is the leading developer, manufacturer and seller of flea control products, and Ciba's market share is approximately 50 percent. Ciba's Program® brand flea control products have a dominant share of the flea control products market. Sandoz ranks second in flea control products sales from sales of its flea control products, under the Vetkem® and Zodiac® brands, and from sales of the active ingredient, methoprene, used by other companies in flea control products. The complaint also alleges that, prior to the merger, Sandoz and Ciba were both developing additional flea control products, which likely would be in direct and substantial competition with each others' products.

The proposed complaint alleges that entry into the flea control products market requires over a decade for chemical synthesis, lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years as well as qualified manufacturing facilities in Order to achieve the required EPA or FDA approvals for commercial sale of these products. Once a product is introduced to the market, extensive sunk costs must be incurred for advertising and promotion to gain significant customer and pet owner acceptance. Despite the expiration of United States patents on methoprene, the base active ingredient used in Sandoz' second generation flea control products, the EPA registrations and proprietary technology involved in the production of methoprene have prevented entry of generic competition to Sandoz' flea control products.

The complaint further alleges that the proposed merger of Ciba and Sandoz would increase the merged firm's ability unilaterally to exercise market power in the flea control products market by combining the two closest substitutes in the market. According to the complaint, the proposed merger would increase the likelihood of coordinated interaction between or among competitors in the flea control products market and eliminate the potential for actual, direct and substantial price competition between them. Consumers would then pay higher prices for flea control products and would not receive the benefits of innovation competition among producers of flea control products.

The proposed Order seeks to remedy the anticompetitive effects of the proposed merger by requiring Sandoz to divest its flea control business for the United States and Canada. Under the Order, the Sandoz flea control business and the Sandoz Dallas facility, which is largely devoted to production of flea control products for the United States and Canada, must be sold to Central Garden and Pet Supply (''Central Garden'') within thirty days after the Order becomes final pursuant to an agreement between Central Garden and Sandoz that will be modified to conform to the terms of the consent Order. Alternatively, Novartis is required by the Order to divest the assets to an alternative acquirer that has received Commission approval, within ninety days after the Order is final. The Order further provides for appointment of a trustee to divest these assets in the vent Sandoz is unable to complete the required divestiture within the specified period. Ciba, Sandoz, and Novartis have entered into an agreement to hold these assets separate from the rest of Ciba, Sandoz, and Novartis pending completion of the divestiture.

The proposed Order also includes a technology transfer agreement to enable the acquirer to produce its own methoprene, the principal active ingredient in the products to be sold pursuant to the Order, as well as a temporary supply agreement to provide methoprene to the acquirer until its own manufacturing capability has achieved necessary government approvals. Some products currently produced at the Dallas facility that are manufactured for sale outside the United States and Canada may continue to be manufactured for Sandoz on behalf of the acquirer for two years.

To ensure the viability of the flea products acquirer, Novartis is prohibited from re-entering the U.S. market with a methoprene-based flea control product for six years. In addition, Novartis is required under the proposed Order to notify the Commission if it plans to acquire flea control assets in the U.S. during the next ten years.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way its terms.

Benjamin I. Berman,

*Acting Secretary.*

Separate Statement of Commissioner Mary L. Azcuenaga in Ciba Geigy Limited, File No. 961–0055

The Commission today accepts a proposed consent order for public comment to settle allegations that the planned merger of Ciba Geigy Ltd. and Sandoz Ltd. would violate Section 7 of the Clayton Act in certain agricultural chemical, pet flea control and gene therapy markets.

There appears to be reason to believe that the proposed merger would be unlawful in the corn herbicide and flea control markets identified in the complaint and that divestiture in each market is the appropriate remedy. Because BASF makes and sells a specialized corn herbicide, the proposed divestiture of Sandoz's corn herbicide business to BASF would not entirely restore pre-merger conditions, but BASF's product is sufficiently differentiated from the divested assets that the minor overlap does not appear to be significant.

It is premature, in my view, to select Central Garden and Pet Supply to acquire Sandoz's flea control business, because the Commission has virtually no information about Central beyond that contained in the proposed order and the Analysis To Aid Public Comment. While the early identification of a candidate to acquire assets to be

divested under an order is to be preferred in order to restore competition quickly, the Commission does not yet have the information to evaluate the competitive implications of a proposed divestiture to Central Garden and Pet Supply.

The alleged gene therapy markets involve products now in clinical trials and others that appear to be more distant in time and perhaps more speculative. The proposed complaint also alleges a technology market, comprising the technology that firms use to develop gene therapies. The theory is that the post-merger combination of Sandoz and Ciba Geigy will control such a critical mass of proprietary information that its incentives to cross license will be diminished, either deterring entry or raising the price of it. I would be interested in public comment on these allegations.

Assuming a violation, it is not entirely clear that the proposed licensing relief is preferable or adequate. A divestiture is the preferred remedy in a Section 7 case. The proposed order, among other things, requires a license of the ex vivo patent, also called the Anderson patent, which was licensed to Sandoz by the National Institutes of Health. The merger does not add to the scope of the patent monopoly, and I see no basis in the proposed complaint for this aspect of the relief. Nor is there any apparent reason why a divestiture in these markets could not be accomplished. I look forward to reviewing the comments on this issue as well.

[FR Doc. 97–5 Filed 1–2–97; 8:45 am]
BILLING CODE 6750–01–P

## GENERAL ACCOUNTING OFFICE

### Federal Accounting Standards Advisory Board

**AGENCY:** General Accounting Office.
**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will meet on Friday, January 17, 1997, from 9:00 A.M. to 4:00 P.M. in room 7C13 of the General Accounting Office building, 441 G St., N.W., Washington, D.C.

The purpose of the meeting is to discuss (1) comments received on the Cost of Capital document, (2) social insurance, (3) Interpretation follow-up, and (4) future agenda items. Also, three new members will be introduced, who will be replacing three retiring members.

Any interested person may attend the meeting is an observer. Board discussions and reviews are open to the public.

**FOR FURTHER INFORMATION CONTACT:** Wendy Comes, Acting Executive Director, 750 First St., N.E., Room 1001, Washington, D.C. 20002, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: December 30, 1996.

Wendy M. Comes,

*Acting Executive Director.*

[FR Doc. 97–71 Filed 1–2–97; 8:45 am]
BILLING CODE 1610–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 96S–0285]**

### Establishment of a Public Docket for Documents and Other Information Pertaining to Exports and Import-for-Export of Certain FDA-Regulated Products Under the FDA Export Reform and Enhancement Act of 1996

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a public docket for documents and other information pertaining to the export and the import-for-export of certain FDA-regulated products (such as drugs, biologics, and devices) under the FDA Export Reform and Enhancement Act of 1996. This action will ensure that this information is equally available to all interested persons on a timely basis.

**ADDRESSES:** The public docket is available under the docket number found in brackets in the heading of this notice and is located in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The public docket may be reviewed between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

**SUPPLEMENTARY INFORMATION:** On April 26, 1996, the President signed the FDA Export Reform and Enhancement Act of 1996 (Pub. L. 104–134) into law. This law significantly alters the statutory requirements for the export of unapproved drugs (including biologics and animal drugs) and devices. The law also permits the importation of components of drugs and devices and food additives, color additives, and dietary supplements into the United States if those components are incorporated into articles (''import-for-export'') that are exported in accordance with the Federal Food, Drug, and Cosmetic Act, as amended.

On August 6, 1996, the President signed Pub. L. 104–180, which included, in section 603, minor technical amendments. The public may obtain a document that sets forth the current statutory provisions (combining the pre-existing law with the amendments made in April and August 1996) on FDA's home page on the Internet (www.FDA.gov).

FDA employees, in the usual discharge of their responsibilities and in response to inquiries and requests from companies, firms, and trade associations, often provide information on FDA's export and import activities. The information provided often addresses historical and current information on statutory or regulatory requirements and on current FDA export and import policies and programs.

To help make information regarding FDA's interpretation and implementation of the FDA Export Reform and Enhancement Act of 1996 available to all interested persons, FDA has developed a mechanism for providing public access to relevant documents and other information created by FDA employees. Specifically, FDA has created a public docket where documents, such as letters on the export of unapproved drugs for investigational use and sent by FDA to various companies and trade associations and guidance to field personnel concerning procedures for articles imported for manufacturing and subsequent export, will be maintained. The documents placed in the public docket are not intended to create or confer any rights for or on any person and do not operate to bind or otherwise obligate or commit FDA or the public to the views expressed. Instead, the documents represent either the agency's current thinking on a particular issue at the time the document was created or at best the best advice of that employee at that time on the issue. (See 21 CFR 10.85(k)).