or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: March 5, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93–5985 Filed 3–16–93; 8:45 am]

BILLING CODE 6560–50–F

[OPP–50756; FRL–4573–6]

Receipt of Notification to Conduct Small-Scale Testing of a Genetically Engineered Microbial Pesticide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received an application (NMP No. 959630–NMP–E) from The Boyce Thompson Institute for Plant Research (BTI) of intent to conduct small-scale field testing of a genetically engineered microbial pesticide. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting public comments on this application.

DATES: Written comments must be received on or before April 16, 1993.

ADDRESSES: Comments in triplicate, must bear the docket control number OPP–50756 and be submitted to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 246, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment(s) concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked, will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Information on the proposed test and all written comments will be available for public inspection in rm. 246 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Phil Hutton, Product Manager (PM) 18, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 213, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703–305–7690).

SUPPLEMENTARY INFORMATION: An application for an NMP has been received from The Boyce Thompson Institute for Plant Research of Tower Road, Ithaca, New York 14853–1801. This NMP application EPA file symbol is 959630–NMP–E. The proposed small-scale field trials involve the introduction of a genetically engineered isolate of the baculovirus pesticide *Lymantria dispar* nuclear polyhedrosis virus (LdMNPV). The test will be conducted to evaluate the co-occlusion baculovirus strategy in a forest ecosystem and will be designed to evaluate the survival capacity and assess the spread of this genetically altered baculovirus pesticide. This strategy involves an engineered virus constructed to lack a polyhedrin gene (poly-minus) and therefore produces only nonoccluded virus particles which are environmentally unstable. By co-infection of individual host cells with the poly-minus engineered virus and a wildtype virus (contains a polyhedrin gene), polyhedrin protein is produced by the wildtype virus which occludes (and protects) both types of virus particles.

The primary difference between the proposed test and the 1989 release is the insertion and expression of the bacterial lacZ gene in the recombinant LdMNPV. The proposed released site which is to be located at the Otis Air National Guard Base on Cape Cod, MA (at least one mile away from any fresh water sources) will consist of 20 closely grouped oak trees. A total of 200 spun bound polyester bags will be attached to the tree limbs. Each bag will contain approximately 500 viral treated gypsy moth eggs and 500 untreated eggs. Following hatch, check bags will be closely monitored to ensure that at least 90 percent of the larvae become infected. Intensive monitoring is planned for 2 years after the release. By the end of the second year, it is anticipated that recovery if the recombinant virus will be at a low level.

Dated: March 5, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93–5865 Filed 3–16–93; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

Policy Statement To Address the Problem of the Use of Large-Value Funds Transfers for Money Laundering

AGENCY: Federal Financial Institutions Examination Council.

ACTION: Statement of policy .

SUMMARY: The Federal Financial Institutions Examination Council (Council) is issuing this policy statement to address the problem of the use of large-value funds transfers for money laundering. The law enforcement community both within the United States and abroad has a growing interest in money laundering through funds transfer systems. The Council supports law enforcement's efforts to identify and prosecute money laundering activities involving large-value funds transfer systems. The Council encourages financial institutions to support law enforcement efforts in this area by including, to the extent practical, complete originator and beneficiary information when sending payment orders, including payment orders sent through Fedwire, CHIPS, and SWIFT.

The FFIEC recommended to its five member agencies that they adopt this Statement of Policy. The FRB, FDIC, NCUA, OCC and OTS have done so.

EFFECTIVE DATE: The FFIEC adopted the policy statement on December 8, 1992.

SUPPLEMENTARY INFORMATION:

Background

The President of the United States has joined with the leaders of other nations to sponsor a Financial Action Task Force (FATF).[1] The FATF is primarily developing international guidelines to facilitate the identification and prosecution of money laundering activities. Historically, law enforcement efforts to curtail money laundering activities have focused on the identification and documentation of currency-based transactions; however, recent investigations have focused on

[1] The FATF was formed as a direct initiative by the Heads of State of Governments of seven major industrialized countries and the President of the European Communities during an economic summit in July 1989. The total membership of FATF now stands at 28 countries, with the primary representation being law enforcement.

the use of funds transfer systems. The FATF has developed recommendations to provide more complete information about the parties to a funds transfer. This information is useful for law enforcement investigations.

FATF Recommendations

The FATF recommends that the text of every payment order include: the name, address, and account number of the person who initiated the first payment order in the funds transfer (the originator); the beneficiary's name and address, and when possible, account number should also be provided in the message text. The FATF also recommends that the identity of the first bank that accepts a payment order from a nonbank should be noted and retained through all subsequent processing of the funds transfer. (The FATF recognizes that the originator and beneficiary information specified in its recommendations may not be provided in transfers originated in some countries because of provisions contained in local laws.)

In this context, SWIFT and CHIPS have recently issued statements encouraging their participants to include the information specified by the FATF recommendations in funds transfers processed through those systems. The Bank of England has also encouraged financial institutions in the United Kingdom to provide complete originator and beneficiary information when using national, international, and proprietary message transfer systems.

To that extent practicable, the Council encourages all domestic banking offices to implement the FATF recommendations when sending a payment order over any funds transfer system, including Fedwire, CHIPS, SWIFT, and any proprietary networks.

With respect to Fedwire, the Council recognizes that the Fedwire format limits the amount of information that can be included in a Fedwire funds transfer. While the Federal Reserve System is exploring changes to the Fedwire format, those changes would require time to implement. In the interim, the Council encourages originating banks to ensure that the nonbank originator, beneficiary, and any instructing bank information is included in each Fedwire funds transfer to the extent possible given the limited size of the Fedwire format and the need to give priority to information necessary for payment processing.

Information concerning the originator and beneficiary may be recorded in the payment order text. For example, if an originator requests depository institution A to transfer funds over Fedwire to a beneficiary of depository institution B, and either the originator or beneficiary information is lengthy and exceeds the space fields specified for originator or beneficiary information, to the extent practicable, the remaining information may be included in the message text in optional fields that may otherwise not be used for that particular payment order.

When a payment order is received by a bank through one funds transfer system and then executed through another funds transfer system; to the extent practical, information on the originator of the payment order received by the intermediary bank should be included in the payment order sent by the intermediary bank. For example, when a SWIFT message is received by an intermediary bank and subsequently sent to the beneficiary's bank via Fedwire, the originator information on the SWIFT message should be carried forward as space permits to the Fedwire message. If the originator information is lengthy and exceeds the space available in the specified fields, to the extent practical, the remaining information may be included in the message text in optional fields that otherwise will not be used for that particular payment order.

Dated: March 11, 1993.

Joe M. Cleaver,

Executive Secretary, Federal Financial Institutions Examination Council.

[FR Doc. 93–6044 Filed 3–16–93; 8:45 am]

BILLING CODE 6210–01–M

FEDERAL MARITIME COMMISSION

Trans-Pacific Freight Conference of Japan; Notice of Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington. DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 206–008600–010.

Title: Agreement No. 8600—Policy Level Agreement.

Parties: Trans-Pacific Freight Conference of Japan, Japan-Atlantic and Gulf Freight Conference.

Synopsis: The proposed amendment changes the name of the Agreement from Agreement No. 8600—Policy Level Agreement to Agreement No. 8600—Japan-U.S. Policy Level Agreement, in order to reflect its application in the trade from Japan to the United States. The amendment also specifically names the conferences as the parties to the Agreement, replacing the ambiguous reference to member lines. Further, it also makes technical and procedural changes to other articles within the Agreement.

Dated: March 11, 1993.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93–6046 Filed 3–16–93; 8:45 am]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research.

Times and Dates: 8 a.m.–5 p.m., April 1, 1993; 8 a.m.–3:15 p.m., April 2, 1993.

Place: Sheraton Suites Hotel, 801 North St. Asaph Street, Alexandria, Virginia 22314.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary of Health and Human Services (HHS), the Assistant Secretary for Health, the Director, CDC, and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), on the establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies. The committee will take into consideration information and proposals provided by the

Department of Energy (DOE), the Advisory Committee for Environment Safety and Health which was established by DOE under the guidelines of a Memorandum of Understanding between HHS and DOE, and other agencies and organizations, regarding the direction HHS should take in establishing the research agenda and in the development of a research plan.

Matters To Be Discussed

The Advisory Committee for Energy-Related Epidemiologic Research will meet to discuss data access, document declassification, and criteria for evaluations/decisions. The National Center for environmental Health (HCEH) will make presentations on:

(1) Proposed radiation epidemiology research;

(2) Proposed environmental dose reconstruction research;

(3) Prioritization of site specific research;

(4) Public involvement;

(5) Molecular epidemiology; and

(6) Air pollution.

Presentations will be made by ATSDR and an update of projects will be provided by the National Institute for Occupational Safety and Health.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Nadine Dickerson, Program Analyst, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4700 Buford Highway, NE. (F–35), Atlanta, Georgia 30341–3724, telephone 404/488–7040, FAX 404/488–7044.

Dated: March 11, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–6078 Filed 3–16–93; 8:45 am]

BILLING CODE 4160–18–M

Availability of Draft USPHS Guidelines for Prevention of Transmission of HIV Through Transplantation of Human Tissue and Organs.

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service (PHS), Department of Health and Human Services.

ACTION: Notice of availability and request for comments.

SUMMARY: This notice announces the availability for review and comment of a draft document entitled "USPHS Guidelines for Prevention of Transmission of HIV Through Transplantation of Human Tissue and Organs," prepared by CDC and other USPHS agencies including the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH).

DATES: To ensure consideration, written comments on this draft document must be received on or before May 17, 1993.

ADDRESSES: Requests for copies of the draft guidelines for prevention of HIV transmission through transplantation must be submitted to the CDC National AIDS Clearinghouse, P.O. Box 6003, Rockville, Maryland 20849–6003, telephone (800) 458–5231. Written comments on this draft document should be sent to the Technical Information Activity, Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop E–49, 1600 Clifton Road, NE., Atlanta, Georgia 30333, for receipt by May 17, 1993.

FOR FURTHER INFORMATION CONTACT: Technical Information Activity, Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop E–49, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

SUPPLEMENTARY INFORMATION: Existing guidelines for prevention of HIV transmission through organ or tissue transplantation have reduced markedly the transmission of HIV via these routes. However, an instance of transmission of HIV from a screened, HIV-antibody-negative organ and tissue donor to several recipients has raised questions about the need for additional Federal oversight of organ and tissue transplantation. A USPHS workgroup, convened to address this problem, concluded that existing guidelines should be reviewed and revised, and asked that CDC be the lead agency for this process. Adequate Federal regulations, recommendations, and guidelines, which are not addressed in this document, are already in place for blood and plasma. This document addresses issues for other tissues and organs including donor screening and testing; quarantine of tissue; inactivation or elimination of infectious organisms in organs and tissues prior to transplantation; timely detection, reporting, and tracking of potentially infected tissues, organs, and recipients; and recall of stored tissue from donors found after donation to have been infected.

Dated: March 10, 1993.

Walter R. Dowdle,

Deputy Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–6079 Filed 3–16–93; 8:45 am]

BILLING CODE 4160–18–P

Food and Drug Administration

[Docket No. 93F–0028]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 3,6-bis(4-chlorophenyl)-2,5-dihydro- pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254) as a colorant in polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 3B4349) has been filed by Ciba-Geigy Corp., 315 Water St., Newport, DE 19804–2434. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of 3,6-bis(4-chlorophenyl)-2,5-dihydro- pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254) as a colorant in polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 8, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–6033 Filed 3–16–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92F-0449]

Hanover Foods Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a petition has been filed on behalf of Hanover Foods Corp. proposing that the food additive regulations be amended to provide for the safe use of calcium disodium EDTA (ethylenediaminetetraacetate) to promote color retention in additional varieties of beans.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9519.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 3A4347) has been filed on behalf of Hanover Foods Corp., P.O. Box 334, Hanover, PA 17331. The petition proposes to amend the food additive regulations in § 172.120 *Calcium disodium EDTA* (21 CFR 172.120) to provide for the safe use of calcium disodium EDTA to promote color retention in additional varieties of beans. The additive is currently approved for use in dried lima beans (cooked, canned) and processed dry pinto beans to promote color retention.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 8, 1993.

Fred R. Shank,

Center for Food Safety and Applied Nutrition.

[FR Doc. 93-6034 Filed 3-16-93; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92E-0470]

Determination of Regulatory Review Period for Purposes of Patent Extension; Actinex® Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Actinex® Cream and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Karin L. Bolte, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Actinex® Cream. Actinex® Cream (masoprocol) is indicated for the topical treatment of actinic (solar) keratoses. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Actinex® Cream (U.S. Patent No. 4,695,590) from Block/Chemex, G.P., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated December 29, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Actinex® Cream represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Actinex® Cream is 3,607 days. Of this time, 2,363 days occurred during the testing phase of the regulatory review period, while 1,244 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: October 22, 1982. FDA has verified the applicant's claim that October 22, 1982, was the date the investigational new drug application became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: April 10, 1989. The applicant claims April 7, 1989, as the date the new drug application (NDA) for Actinex® Cream (NDA 19-940) was initially submitted. However, FDA records indicate that NDA 19-940 was initially submitted on April 10, 1989.

3. *The date the application was approved*: September 4, 1992. FDA has verified the applicant's claim that NDA 19-940 was approved on September 4, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 712 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 17, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 13, 1993, for a

determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 10, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–6036 Filed 3–16–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0507]

Determination of Regulatory Review Period for Purposes of Patent Extension; Desogen®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Desogen® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Karin L. Bolte, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Desogen®. Desogen® (desogestrel and ethinyl estradiol) is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Desogen® (U.S. Patent No. 3,927,046) from Akzona, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated December 31, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Desogen® represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Desogen® is 1,427 days. Of this time, 716 days occurred during the testing phase of the regulatory review period, while 711 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* January 15, 1989. FDA has verified the applicant's claim that January 15, 1989, was the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 31, 1990. FDA has verified the aplicant's claim that December 31, 1990, was the date the new drug application (NDA) for Desogen® (NDA 20–071) was initially submitted.

3. *The date the application was approved:* December 10, 1992. FDA has verified the applicant's claim that NDA 20–071 was approved on December 10, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,504 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 17, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 13, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 10, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–6035 Filed 3–16–93; 8:45 am]

BILLING CODE 4160–01–F