or Meeting Facilities: 200 Reporting hours.

FOR FURTHER INFORMATION CONTACT: Mary L. Cunningham, (202) 501–2691.

Copy of Proposal: May be obtained from the Information Collection Management Branch (CAIR), 7102, GSA Building, 18th & F Street NW., Washington, DC 20405, by telephoning (202) 501–2691, or by faxing your request to (202) 501–2727.

Dated: January 27, 1993.

Emily C. Karam,

Director, Information Management Division.

[FR Doc. 93–3011 Filed 2–8–93; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Auditory Effects of Exposure to Noise and Industrial Chemicals; Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) and the Pan American Health Organization announce the following meeting.

Name: Auditory Effects of Exposure to Noise and Industrial Chemicals.

Time and Dates: 9 a.m.–4 p.m. February 16–17, 1993.

Place: Robert A. Taft Laboratories, Main Auditorium, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Status: Open to the public, limited only by the space available.

Purpose: The purpose of this meeting is to provide an overview of key studies of hearing loss from exposure to noise and industrial chemicals and to solicit individual input to be used in the development of a protocol for the study of hearing sensitivity in workers exposed to noise and chemicals. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited.

Contact Person for Additional Information: Derek E. Dunn, Ph.D., NIOSH, CDC, 4676 Columbia Parkway, Mailstop C27, Cincinnati, Ohio 45226, telephone 513/533–8281.

Dated: February 3, 1993.

Elvin Hilyer,

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

[FR Doc. 93–3029 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–19–M

Board of Scientific Counselors, National Institute for Occupational Safety and Health; 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 meeting.

Name: Board of Scientific Counselors, National Institute for Occupational Safety and Health (NIOSH) Meeting.

Times and Dates: 9 a.m.–4:30 p.m., February 24, 1993; 9 a.m.–12 noon, February 25, 1993.

Place: Terrace Garden Inn-Buckhead, Sunflower Room, 3405 Lenox Road, NE, Atlanta, Georgia 30326.

Status: Open to the public, limited only by the space available.

Purpose: The board provides guidance on NIOSH research activities related to developing and evaluating hypotheses, systematically documenting findings, and disseminating results.

Matters to be Discussed: The agenda will include the NIOSH Director's report; legislative and budget update; review and discussion of the NIOSH programs on fiber research, surveillance, and psychological disorders; presentation on a new vision for NIOSH; and an overview of a planned workshop on engineering controls for infectious agents. Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Roy M. Fleming, Sc.D., Executive Secretary, Office of the Director, NIOSH, CDC, 1600 Clifton Road, NE., Mailstop D–30, Atlanta, Georgia 30333, telephone 404/639–3343.

Dated: February 3, 1993.

Elvin Hilyer,

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

[FR Doc. 93–3030 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–19–M

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings.

ADDRESSES: Copies are available for public examination at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 301–443–1751.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. App. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 1991, through September 30, 1992:

Center for Biologics Evaluation and Research: Biological Response Modifiers Advisory Committee, Blood Products Advisory Committee, Vaccines and Related Biological Products Advisory Committee.

Center for Drug Evaluation and Research: Anesthetic and Life Support Drugs Advisory Committee, Antiviral Drugs Advisory Committee, Arthritis Advisory Committee, Cardiovascular and Renal Drugs Advisory Committee, Drug Abuse Advisory Committee, Gastrointestinal Drugs Advisory Committee, Generic Drugs Advisory Committee, Medical Imaging Drugs Advisory Committee, Oncologic Drugs Advisory Committee, Peripheral and Central Nervous System Drugs Advisory Committee.

Center for Veterinary Medicine: Veterinary Medicine Advisory Committee.

National Center for Toxicological Research: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

Annual reports are available for public inspection at: (1) The Library of Congress, Newspaper and Current Periodical Reading Room, rm. 133, Madison Bldg., 101 Independence Ave. SE., Washington, DC; and (2) the Dockets Management Branch (HFA–305), rm.1–23, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–3045 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0379]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined

the regulatory review period for Produciil® 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 animal 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: John S. Ensign, 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product Produciil® (efrotomycin). Produciil® is indicated for increased weight gain when incorporated into complete swine feeds at 3.6 to 14.5 grams per ton; in addition, it is indicated for improved feed efficiency when incorporated into complete swine feeds at 3.6 grams per ton. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Produciil© (U.S. Patent No. 4,024,251) from Merck & Co., 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 October 26, 1992, advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of Produciil® represented the first commercial marketing 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 Produciil® is 5,186 days. Of this time, 2,965 days occurred during the testing phase of the regulatory review period, while 2,221 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: May 15, 1978. FDA has verified the applicant's claim that the investigational new animal drug application (INADA) became effective on May 15, 1978.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: June 26, 1986. The applicant claims that June 23, 1986, was the date the new animal drug application (NADA) for Produciil® (NADA 140–818) was submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgment letter assigning a number to NADA 140–818 was June 26, 1986, which is considered to be the submission date for the NADA.

3. *The date the application was approved*: July 24, 1992. FDA has verified the applicant's claim that NADA 140–818 was approved on July 24, 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 1,095 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 12, 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 August 8, 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: January 22, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–3042 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

Board of Tea Experts; Rechartering

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rechartering of the Board of Tea Experts by the Commissioner of Food and Drugs or designee. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (5 U.S.C. App. 2).

DATES: Authority for this board will expire on January 3, 1995, unless the Commissioner or designee formally determines that rechartering is in the public interest.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 12420 Parklawn Dr., Rockville MD 20857, 301–443–2765.

Dated: January 21, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–3044 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

Technical Electronic Product Radiation Safety Standards Committee; Recharter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration announces the rechartering of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), by the Commissioner of Food and Drugs or designee. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (5 U.S.C. App. 2).

DATES: The new charter for this committee will extend to December 24, 1994.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 12420 Parklawn Dr., Rockville MD 20857, 301–443–2765.

Dated: January 21, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–3046 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0491]

Manna Pro Corp.; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Manna Pro Corp. The NADA provides for the use of a nicarbazin Type A article for making tylosin Type C chicken feeds. The sponsor requested the withdrawal of approval.

EFFECTIVE DATE: February 19, 1993.

FOR FURTHER INFORMATION CONTACT: Vitolis E. Vengris, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8749.

SUPPLEMENTARY INFORMATION: Manna Pro Corp., P.O. Box 11851, Fresno, CA 93775, is the sponsor of NADA 10–175, which provides for the use of a nicarbazin Type A article for making tylosin Type C chicken feeds. In its letter dated October 9, 1992, the sponsor requested that FDA withdraw approval of the NADA because the product is no longer marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 10–175 and all supplements and amendments thereto is hereby withdrawn, effective February 19, 1993.

Dated: January 28, 1993.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93–3048 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92F–0475]

SCM Chemicals; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that SCM Chemicals has filed a petition proposing that the food additive regulations be amended to provide for the safe use of phosphorylated tall oil fatty acids as pigment dispersants in polymeric films intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

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 3B4350) has been filed by SCM Chemicals, c/o 1100 G St. NW., Washington, DC 20001. The petition proposes to amend the food additive regulations to provide for the safe use of phosphorylated tall oil fatty acids as pigment dispersants in polymeric films 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: January 13, 1993.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–3049 Filed 2–9–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0499]

Lyphomed, Division of Fujisawa USA, Inc.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of withdrawal of 10 Abbreviated New Drug Applications that appeared in the **Federal Register** of January 7, 1993 (58 FR 3027). The document was published with an incorrect date of signature. This document corrects that error.

SUPPLEMENTARY INFORMATION: In FR Doc. 93–242, appearing on page 3027, in the **Federal Register** of January 7, 1993, the following correction is made: On page 3028, in the first column, the date line that appears above the signature, which now reads "December 15, 1991." is corrected to read "December 15, 1992."

Dated: January 29, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–3047 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0427]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZEBETA® 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: Brian J. Malkin, 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 ZEBETA® (bisoprolol fumarate). ZEBETA® is indicated in the management of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZEBETA® (U.S. Patent No. 4,258,062) from E. Merck GmbH, 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 November 13, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZEBETA® represented the first commercial marketing 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 ZEBETA® is 2,874 days. Of this time, 1,778 days occurred during the testing phase of the regulatory review period, while 1,096 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:* September 19, 1984. The applicant claims September 16, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1984, which was 30 days after FDA receipt of the IND.

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:* August 1, 1989. The applicant claims July 28, 1989, as the date the new drug application (NDA) for ZEBETA® (NDA 19–982) was filed. However, FDA records indicate that NDA 19–982 was submitted on August 1, 1989.

3. *The date the application was approved:* July 31, 1992. FDA has verified the applicant's claim that NDA 19–982 was approved on July 31, 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 2 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 12, 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 August 9, 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: January 21, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–3050 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0471]

Determination of Regulatory Review Period for Purposes of Patent Extension; Suprane™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Suprane™ 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: Nicholas P. Reuter, 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 Suprane™. Suprane™ (desflurane) is indicated as an inhalation agent for induction or maintenance of anesthesia for inpatient and outpatient surgery in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Suprane™ (U.S. Patent No. 4,762,856) from Anaquest, 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 15, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Suprane™ represented the first commercial marketing 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 Suprane™ is 1,369 days. Of this time, 771 days occurred during the testing phase of the regulatory review period, while 598 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*: December 21, 1988. FDA has verified the applicant's claim that December 21, 1988, 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*: January 30, 1991. FDA has verified the applicant's claim that January 30, 1991, was the date the new drug application (NDA) for Suprane™ (NDA 20–118) was initially submitted.

3. *The date the application was approved*: September 18, 1992. FDA has verified the applicant's claim that NDA 20–118 was approved on September 18, 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 406 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 12, 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 August 8, 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: January 21, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–3043 Filed 2–9–93; 8:45 am]

BILLING CODE 4160–01–F

Report of the FDA Task Force on International Harmonization; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Report of the FDA Task Force on International Harmonization." This report provides an overview of FDA's international activities and describes the importance of international harmonization efforts as they affect the safety, effectiveness, and quality of products regulated by FDA.

ADDRESSES: The "Report of the FDA Task Force on International Harmonization" may be ordered from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. Orders must reference NTIS order number PB93–128155 and include payment of $52 for each copy of the document. Payment may be made by check, money order, charge card (American Express, VISA, or MasterCard), or billing arrangements made with NTIS. Charge card orders must include the charge card account number and expiration date. For telephone orders or further information on placing an order, call NTIS at 703–487–4650.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of Health Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4480.

SUPPLEMENTARY INFORMATION: In December 1991, the Commissioner of Food and Drugs formed the FDA Task Force on International Harmonization to assess the goals, scope, and direction of FDA's participation in international harmonization. Following an indepth study of FDA international activities, including the interviewing of many FDA constituency groups, the task force made eight recommendations for enhancing FDA's international programs.

This report provides an overview of FDA's current international harmonization efforts, describes the importance of assuring consistent scientifically based standards for food, drugs, human biologics, medical devices, and radiation emitting products, and it relates these efforts to the protection of public health. The report also documents the pressures, incentives, and broad public support for active FDA participation in international harmonization programs.

The report is available for purchase from NTIS (address above).

Dated: January 29, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–3041 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Preventive Health Amendments of 1992; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority from the Secretary to the Assistant Secretary for Health on January 14, 1981 (46 FR 10016), the Assistant Secretary for Health has delegated to the Director, Centers for Disease Control and Prevention, with authority to redelegate, all the authorities pertaining to the National Foundation for the Centers for Disease Control and Prevention under part N, title III of the Public Health Service Act (42 U.S.C. 241 *et seq.*), as amended. This