Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: January 18, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 00–1884 Filed 1–26–00 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

NAME: National Committee on Vital and Health Statistics (NCVHS).

TIME AND DATE: 1:30–3:30 EST, February 2, 2000.

PLACE: Conference Call, Participants Dial-in Number: 1–888–422–7105, Participants Code: 348362.

STATUS: Open.

PURPOSE: During this conference call, the Committee will discuss the Notice of Proposed Rule Making (NPRM) issued by HHS on Standards for Privacy of Individually Identifiable Health Information and review draft comments on the NPRM developed by the Subcommittee on Privacy.

NOTICE: This conference call is open to the public using the participants' dial-in telephone number and participants' code, but access may be limited by the number of available telephone lines.

CONTACT PERSON FOR MORE INFORMATION: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Gail Horlick, M.S.W., J.D., Lead Staff Person for the NCVHS Subcommittee on Privacy and Confidentiality, Program Analyst, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E–62, Atlanta, Georgia 30333, telephone (404)–639–8345; or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: http://www.ncvhs.hhs.gov/, where further information will be posted when available.

Dated: January 19, 2000.

James Scanlon,

Director, Division of Data Policy Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 00–1885 Filed 1–26–00; 8:45 am]

BILLING CODE 4151–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0852]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Maxalt® 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Maxalt® (rizatriptan benzoate). Maxalt® is indicated for the acute treatment of migraine attacks, with or without aura in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Maxalt® (U.S. Patent No. 5,298,520) from Merck & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 11, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Maxalt® represented the first permitted 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 Maxalt® is 2,099 days. Of this time, 1,734 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* October 1, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 1, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* June 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Maxalt® (NDA 20–864) was initially submitted on June 30, 1997.

3. *The date the application was approved:* June 29, 1998. FDA has

verified the applicant's claim that NDA 20–864 was approved on June 29, 1998.

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 153 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 27, 2000, 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 July 25, 2000, 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: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–1865 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–0118]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Arava® 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: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Arava® (leflunomide). Arava® is indicated in adults for the treatment of active rheumatoid arthritis to reduce signs and symptoms and to retard structural damage as evidenced by X-ray erosions and joint space narrowing. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Arava® (U.S. Patent No. 4,284,786) from Hoechst Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 17, 1999, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Arava® represented the first permitted 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 Arava® is 2,032 days. Of this time, 1,908 days occurred during the testing phase of the regulatory review period, while 124 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* February 18, 1993. The applicant claims February 14, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 18, 1993, 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 of the act:* May 10, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Arava® (NDA 20–905) was initially submitted on May 10, 1998.

3. *The date the application was approved:* September 10, 1998. FDA has verified the applicant's claim that NDA 20–905 was approved on September 10, 1998.

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 1,110 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 27, 2000, 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 July 25, 2000, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition