DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0293]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Skelid® 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: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Skelid® (tiludronate disodium). Skelid® is indicated for treatment of Paget's disease of bone (osteitis deformans). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Skelid® (U.S. Patent No. 4,876,248) from Sanofi Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Skelid® 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 Skelid® is 2,013 days. Of this time, 1,639 days occurred during the testing phase of the regulatory review period, 374 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*: September 4, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 4, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: February 28, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Skelid® (NDA 20–707) was initially submitted on February 28, 1996.

3. *The date the application was approved*: March 7, 1997. FDA has verified the applicant's claim that NDA 20–707 was approved on March 7, 1997.

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 1,192 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 8, 1998, 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 April 7, 1999, 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: September 28, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–27078 Filed 10–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 2, 1998, 8:30 a.m. to 5 p.m.

Location: Gaithersburg Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications (NDA's) 20–977 (tablets) and 20–978 (oral solution) for abacavir sulfate (Ziagen, Glaxo Wellcome, Inc.) for the treatment of human immunodeficiency virus (HIV) infection.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 26, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 26, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 2, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–27082 Filed 10–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

1998 FDA Science Forum on Biotechnology: Advances, Applications, and Regulatory Challenges

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA's) Office of Science is announcing the following meeting: ''1998 FDA Science Forum on Biotechnology: Advances, Applications, and Regulatory Challenges.'' The meeting will bring FDA scientists together with representatives of industry, academia, government agencies, consumer groups, and the public to discuss the impact of the enormous advances in biotechnology on product development and regulation. The program will encompass bioengineered products, novel therapeutic and preventive approaches, diagnostics and detection methodologies, and safety and efficacy assessment.

Date and Time: The meeting will be held on December 8, 1998, 8:30 a.m. to 6 p.m., and December 9, 1998, 8:30 a.m. to 5 p.m.

Location: Washington Convention Center, rms. 30–33 (lower level) and Hall C (upper level), 900 Ninth St. NW., Washington, DC.

Contact: Susan A. Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3366, e-mail ''shomire@bangate.fda.gov'' or American Association of Pharmaceutical Scientists 703–518–8429, e-mail ''meetings@aaps.org''.

Registration: December 8 and 9, 1998, 7 a.m. to 8:30 a.m. Registration and program information are available on the Internet at ''http://www.aaps.org/edumeet.html''. Attendance will be limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact the American Association of Pharmaceutical Scientists at least 3 weeks in advance.

Dated: October 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27081 Filed 10–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Consumer Forum; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: ''National Consumer Forum.'' This forum will provide an opportunity for consumers and older Americans to engage in an open dialogue with senior FDA officials on specific health concerns and consumer protection issues. These types of forums enable the agency to better determine the level of public interest in its current policies, as well as to promote a better understanding of consumer issues and concerns.

Date and Time: The meeting will be held on Monday, October 19, 1998, from 1 p.m. to 4 p.m.

Location: The meeting will be held at the Department of Health and Human Services, Hubert Humphrey Bldg., Great Hall, 200 Independence Ave. SW., Washington, DC.

Contact: Synthia E. Jenkins, Office of Consumer Affairs (HFE–40), Food and Drug Administration, 5600 Fishers Lane, 301–827–4412, FAX 301–443–9767.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), to the contact person by October 15, 1998.

If you need special accommodations due to a disability, please contact Synthia E. Jenkins at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: October 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27338 Filed 10–7–98; 12:38 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0546]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling Regulations (21 CFR Parts 101, 102, 104, and 105)'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug