DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic 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 March 23, 1999, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20057, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–051 Temodal® (temozolomide) Capsules, Schering Corp., indicated for the treatment of patients with advanced metastatic malignant melanoma.

Procedure: On March 23, 1999, from 8 a.m. to 12:15 p.m., the meeting is open to the public. 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 March 8, 1999. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 1999, 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. After the scientific presentations, a 15-minute open public session will be conducted for interested persons who have submitted their request to speak by March 8, 1999, to address issues specific to the submission or topic before the committee.

Closed Committee Deliberations: On March 23, 1999, from 1 p.m. to 5:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The investigational new drug application and Phase I and Phase II drug products in process will be presented, and recent action on selected NDA's will be discussed. This portion of the meeting will be closed to permit discussion of this information.

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

Dated: February 22, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–4876 Filed 2–26–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0794]

Determination of Regulatory Review Period for Purposes of Patent Extension; Zemplar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Zemplar 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 Zemplar (paricalcitol). Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Zemplar (U.S. Patent No. 5,246,925) from Wisconsin Alumni Research Foundation, 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 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Zemplar 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 Zemplar is 1,079 days. Of this time, 623 days occurred during the testing phase of the regulatory review period, while 456 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*: May 6, 1995. The applicant claims April 30, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 6, 1995, 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*: January 17, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Zemplar (NDA 20–819) was initially submitted on January 17, 1997.

3. *The date the application was approved: April 17, 1998*. FDA has verified the applicant's claim that NDA 20–819 was approved on April 17, 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 574 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 30, 1999, 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 30, 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: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–4877 Filed 2–26–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Health Education Assistance Loan (HEAL) Program: Lender's Application for Insurance Claim Form and Request for Collection Assistance Form (OMB No. 0915–0036)—Extension

This clearance request is for a revision of two forms that are currently approved by OMB. HEAL lenders use the Lenders Application for Insurance Claim to request payment from the Federal Government for federally insured loans lost due to borrowers' death, disability, bankruptcy, or default. The Lenders Application for Insurance Claim form has been revised to reflect information necessary to approve a claim and is substantiated in supporting documentation submitted with each claim request. These revisions will facilitate the Department's efforts towards electronic claim request submissions. The Request for Collection Assistance form is used by HEAL lenders to request federal assistance with the collection of delinquent payments from HEAL borrowers. No changes are proposed for the Request for Collection Assistance form.

The estimates of annualized burden are as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Lender's Application for Insurance Claim	20	75	1,500	30 minutes	750
Request for Collection Assistance	20	1,260	25,200	10 minutes	4,208
Total Burden	20				4,958