ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
In-depth Interview	540	1	2/3	360

Estimated Total Annual Burden Hours: 360.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 1, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–5777 Filed 3–8–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–1071]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Provigil 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, 301–594–2041.

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 Provigil (modafinil). Provigil is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Provigil (U.S. Patent No. 4,177,290) from Cephalon, 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 10, 1999, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Provigil represented the first permitted commercial marketing or use of the product. Later, 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 Provigil is 1,975 days. Of this time, 1,250 days occurred during the testing phase of the regulatory review period, while 725 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*: July 30, 1993. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 30, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 30, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Provigil (NDA 20–717) was initially submitted on December 30, 1996.

3. *The date the application was approved*: December 24, 1998. FDA has verified the applicant's claim that NDA 20–717 was approved on December 24, 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 985 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by May 8, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the

applicant for extension acted with due diligence during the regulatory review period by September 5, 2001. 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. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be 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, 2001.

Jane A. Axlerad,

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

[FR Doc. 01–5812 Filed 3–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1817]

Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors.'' This guidance describes the special controls FDA believes will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the home uterine activity monitors (HUAM's) from class III to class II.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5 diskette of the guidance document entitled ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document describes a means by which manufacturers of HUAM's may comply with the requirements of special controls for class II devices. Designation of this guidance as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate HUAM should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

The guidance document addresses such areas as: Intended use and indications for use; labeling; design controls; clinical data; patient registry; preclinical data including electrical safety testing, electromagnetic compatibility, software, device accuracy, material safety, and cleaning and disinfection.

This guidance document was issued for public comment in the **Federal Register** of July 30, 1999 (64 FR 41443), as a draft guidance entitled ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications.'' The document has been modified from the original draft version for purposes of clarity and adding detail regarding the device description, bench testing, and design controls.

II. Significance of Guidance

This guidance document represents the agency's current thinking on premarket notifications for HUAM's. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), and published the final rule which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 final guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors'' via your fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (820) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets