and on consultation with industry, FDA estimates that preparation of reports and information required by this section require 5,805 hours (135 hours per respondent).

3. § 814.84—Reports: 430 Burden Hours

Postapproval requirements described in § 814.82 (above) require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on a periodic basis. As stated previously, the range of PMAs fitting this category averaged approximately 43 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section take 430 hours.

The total hours for statutory burden is 1,750. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was derived to forecast future expectations with regard to this statutory data.

B. Recordkeeping

The recordkeeping burden in this section involves the maintenance of records used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records would be required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved and 75 percent of those have original clinical trial data. Therefore, approximately 43 PMAs a year (62 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of active PMA applications must maintain these records. PMAs have been required since 1976, and there are 900 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and, at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 900 holders of approved original PMAs, therefore, is 15,300 hours (900 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12277 Filed 5–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1412]

Determination of Regulatory Review Period for Purposes of Patent Extension; Uvasorb HA88

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Uvasorb HA88 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 that claims that food additive.

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 as 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 food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive 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 food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. section 156(g)(2)(B).

FDA recently approved for marketing the food additive Uvasorb HA88. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Uvasorb HA88 (U.S. Patent No. 4,477,615) from 3V Partecipazioni Industriali S.p.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 4, 2000, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of Uvasorb HA88 represented the first permitted commercial marketing or use of the product. Subsequently, 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 Uvasorb HA88 is 3,482 days. Of this time, 684 days occurred during the testing phase of the regulatory review period, and 2,798 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test (test) involving this food additive additive product was begun*: November 2, 1989. FDA has verified the applicant's claim that the test was begun on November 2, 1989.

2. *The date the petition requesting the issuance of a regulation for use of the additive (petition) was initially*

submitted with respect to the food additive product under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348): September 16, 1991. FDA has verified the applicant's claim that the petition was initially submitted on September 16, 1991.

3. *The date the petition became effective: May 14, 1999.* FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on May 14, 1999.

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 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by July 16, 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 November 12, 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: March 2, 2001.

Jane A Axelrad,

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

[FR Doc. 01–12228 Filed 5–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0191]

Medical Devices; Global Harmonization Task Force; Study Group 1; Working Draft ''Medical Devices Classification;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft document entitled ''Medical Devices Classification.'' Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this document on premarket regulation of medical devices. This document is intended to provide information only and represents a harmonized proposal that may be used by governments developing or updating their premarket regulation schemes for medical devices. This draft document is not being issued as an FDA guidance. Elements of the approach set forth in this document may not be consistent with current U.S. regulatory requirements. However, FDA is publishing the draft at this time to give the public an opportunity to comment on the document before the agency resumes discussions with other countries. Public comments will help FDA decide whether and how the agency can adapt these recommendations to our own regulatory requirements.

DATES: Submit written comments concerning this at any time. FDA must submit its comments on this draft to GHTF by July 1, 2001. FDA will consider any comments that it receives after it prepares its comments for GHTF in future discussions with GHTF on this issue.

ADDRESSES: Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the document. Submit written requests for single copies on a 3.5″ diskette of the draft document entitled ''Medical Devices Classification'' 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.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. The GHTF was established in 1992 to facilitate medical device harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world. The most recent GHTF meeting was held in September 2000, in Ottawa, Canada. The GHTF is a voluntary consortium of representatives from medical device regulatory authorities and trade associations from around the world, including Canada, Japan, and the European Union.

The objective of the GHTF is to encourage harmonization of regulatory systems for medical devices in order to facilitate trade while recognizing the right of participating members to enforce regulatory requirements considered most suitable to protect the public health of their citizens. One of the ways this objective is achieved is by identifying and developing areas of international cooperation that can reduce differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by Study Group 1.

Study Group 1 was formed in January 1993, and was originally tasked with identifying differences between various premarket regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and offer guidance that could help lead to harmonization. As a result of their efforts, this group has developed the document entitled ''Medical Devices Classification.'' This GHTF document suggests some general guidelines for classification of medical devices to encourage harmonization. It recommends that there is a need to classify medical devices based on their risk to patients, users, and other persons; and that there is a benefit for manufacturers and regulatory authorities if a globally harmonized classification system is developed. The