TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891–Initial Establishment. Registration	1,462	1	1,462	.25	366
807.22(b)	Form 2892–Device Listing (initial and update)	5,640	1	5,640	.50	2,820
807.22(a)	Form 2891a–Registration Update	22,000	1	22,000	.25	5,500
807.31(e)		200	1	200	.50	100
TOTALS						8,786

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.31	7,900	10	79,000	0.5	39,500
TOTALS					39,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 8,786 hours, and recordkeeping burden hours for respondents is estimated to be 39,500 hours. The estimates cited in the tables above are based primarily upon the annual FDA Accomplishment Report, which includes actual FDA registration and listing figures from fiscal year (FY) 1997. These estimates are also based on conversations with industry and trade association representatives, and internal review of the FDA forms and documents referred to in the previous tables.

According to 21 CFR part 807, all owners/operators are required to list, and establishments are required to register. Each owner/operator has an average of two establishments, according to statistics gathered from FDA's Registration and Listing Data Base. The data base has 22,000 establishments listed in it. Based on past experience, the agency anticipates that approximately 1,462 registrations will be processed annually, and that 5,640 initial and update device listings will be submitted. Although FDA only processed 12,237 annual registrations during FY 1997 due to a delay in sending out the annual registration forms, the normal amount of processing of annual registrations in the past has been 22,000. FDA anticipates reviewing 200 historical files annually. Finally, because initial importers (currently estimated at 6,200) do not have to maintain historical files, FDA estimates that the number of recordkeepers required to maintain the initial historical information will be 7,900 (which is the number of establishments, 22,000 minus the number of initial importers, 6,200, divided by 2, the average number of establishments per owner/operator).

Dated: July 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18877 Filed 7–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0271]

Determination of Regulatory Review Period for Purposes of Patent Extension; PANDEL Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PANDEL Cream 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 PANDEL Cream (hydrocortisone buteprate). PANDEL Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PANDEL Cream (U.S. Patent No. 4,290,962) from Taisho Pharmaceutical Co. Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PANDEL Cream 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 PANDEL Cream is 4,165 days. Of this time, 3,078 days occurred during the testing phase of the regulatory review period, 1,087 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 6, 1985. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 6, 1985.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: March 10, 1994. The applicant claims March 1, 1994, as the date the new drug application (NDA) for PANDEL Cream (NDA 20–453) was initially submitted. However, FDA records indicate that NDA 20–453 was submitted on March 10, 1994.

3. *The date the application was approved*: February 28, 1997. FDA has verified the applicant's claim that NDA 20–453 was approved on February 28, 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 1,096 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 14, 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 January 12, 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: June 23, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–18878 Filed 7–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0508]

Medical Devices: Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance.'' The draft guidance document has been created by members of the International Global Harmonization Task Force Study Group 3 (GHTF SG3) to propose harmonized international process validation technical requirements and guidance for the manufacture of medical devices. The agency is requesting public comment regarding the draft guidance document as proposed by the GHTF SG3. Because FDA intends to utilize the GHTF document as guidance for the agency and industry, FDA is also publishing this document for comment under its good guidance practices (GGP's).

DATES: Written comments concerning this draft guidance document must be received by August 14, 1998.

ADDRESSES: Submit written comments concerning the draft guidance document entitled ''Draft Global Harmonization Task Force Study Group 3 Process Validation 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. Submit written requests for single copies on a 3.5'' diskette of the draft guidance document 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Collin L. Figueroa, Center for Devices and Radiological Health (HFZ–341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by governmental regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in numerous efforts to enhance this harmonization and has expressed its commitment to promote the international harmonization of regulatory requirements. As part of this effort, FDA has been actively involved in a Global Harmonization Task Force (GHTF). The GHTF has subsequently formed four study groups, each tasked with aspects designed to facilitate global harmonization.

Study Group 3 of the GHTF drafted the process validation guidance to harmonize quality systems requirements