Services' Office of International Affairs, other government and nongovernment organizations, and academic institutions, as appropriate.

Office of the Director (CAB1). (1) Manages, directs, and coordinates the activities of the OGH; (2) provides leadership in developing OGH policy, program planning, implementation, and evaluation; (3) coordinates the management of legislated international ceiling exempt positions; (4) coordinates the CDC cable clearance function; (5) provides for the orientation and scheduling of foreign visitors to CDC; (6) provides CDC support services related to international travel, such as the acquisition of passports, visas, and international clearances; (7) maintains international travel database and develops related reports; (8) serves as the CDC focal point for information regarding CDC's overseas assignees.

Dated: July 7, 1998.

Claire V. Broome, M.D.,

Acting Director.

[FR Doc. 98–18935 Filed 7–15–98; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0494]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for domestic manufacturers and initial importers of devices to register their establishments and list their devices.

DATES: Submit written comments on the collection of information by September 14, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301827–1223

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Registration and Listing—21 CFR 807

Section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) requires that manufacturers and initial importers engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and in commercial distribution register their establishments and list the devices they manufacture with FDA. This is accomplished by completing FDA Form 2891, ''Initial Registration of Device Establishment'' and FDA Form 2892, ''Medical Device Listing.'' In addition, each year active, registered establishments must notify FDA of changes to the current registration and device listing for the establishment. Annual changes to current registration information are pre-printed on FDA Form 2891a and sent to registered establishments. The form must be sent back to FDA's Center for Devices and Radiological Health (CDRH), even if no changes have occurred. Changes to listing information are submitted on Form 2892. Refurbishers/reconditioners are not required to register or list; however, FDA will accept voluntary registration and listings from firms that wish to be registered with FDA.

In addition, under § 807.31 (21 CFR 807.31), each owner or operator is required to maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements above, the owner or operator must be prepared to submit to FDA upon specific request all labeling and advertising mentioned above (§ 807.31(e)).

The information collected through these provisions is used by FDA to identify firms subject to FDA's regulations and is used to identify geographic distribution in order to effectively allocate FDA's field resources for these inspections and to identify the class of the device which determines the inspection frequency. When complications occur with a particular device or component, manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection will be domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

FDA estimates the burden of this collection of information as follows:

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