Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
.....	113	1	2	227
Staff Questionnaire	190	1	1	190
Estimated Total Annual Burden Hours:	.....	.....	.....	2,146

Additional Information: Copies of the proposed collection of information can be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource management, 370 L'Enfant Promenade, S.W., Washington, DC 20047, Attn.: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 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: Ms. Wendy Taylor.

Dated: August 3, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–21111 Filed 8–6–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0515]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Amendments to Humanitarian Use Device (HUD) Requirements

Section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)) was created as an incentive for the development of HUD's for use in the treatment or diagnosis of diseases or conditions affecting fewer than 4,000 individuals in the United States. FDA is issuing this rule to amend the existing regulations governing HUD's, found in part 814 (21 CFR part 814), to conform to the amendments made by the Food and Drug Administration Modernization Act of 1997 (FDAMA) to section 520(m) of the act.

In the **Federal Register** of April 17, 1998 (63 FR 19185), the agency requested comments on the proposed collection of information amending the regulations governing HUD's. FDA received one comment concerning the information collection provisions of the rule. A summary of the comment and FDA's response is provided as follows.

The comment objected to the annual reporting requirement and suggested that FDA determine the appropriate reporting period at the time of product approval rather than always requiring reporting on an annual basis.

FDA has modified the rule in response to this comment. Under the final rule of June 26, 1996 (61 FR 33232), a humanitarian device exemption (HDE) holder was required to obtain approval of an extension request every 18 months in order to continue marketing the HUD. FDAMA eliminated this requirement but provided that FDA may require the holder to demonstrate continued compliance with the HDE requirements if the agency believes that such demonstration is needed to protect the public health or has reason to believe that the criteria for the exemption are no longer met.

FDA included a provision for annual reporting in the proposed rule because the agency believed that annual reporting would be the most appropriate mechanism for the agency to monitor whether there is reason to question the continued exemption of the device from the act's effectiveness requirements. Upon reconsideration, FDA has determined that the reporting frequency necessary to protect the public health may vary depending upon the device, its intended use, the affected patient population, and experience with the device after it is marketed. Therefore, § 814.126(b)(1) has been modified in the final rule to state that the frequency of the reports will be specified in the approval order for the HDE. Ordinarily, FDA does not expect to require periodic reports to be submitted more frequently than annually. FDA does believe, however, that it may be appropriate to require reports on certain HDE's less frequently and that in many cases the frequency of required reports will decrease after the device has been marketed for a period of time.

FDA estimates that, due to the nature of some of the devices, initially 15 HDE holders per year will be required to submit annual reports. As the agency and industry gain experience with HDE's, FDA believes the number of HDE holders who will be required to submit annual reports will decrease. FDA believes that much of the information will already be in the HDE holder's possession, and the agency estimates that the reports will take an average of 120 hours per response.

The same comment also objected to the ''requirement'' that an ''HDE holder maintain records in perpetuity * * *'' and suggested that a more appropriate timeframe would be 3-calendar years after the manufacturer ceases distribution of the product in question.

Section 814.126(b)(2) of the HDE regulation specifies the types of records that should be maintained by the HDE holder, but does not specify the

timeframe for maintaining such records. FDA agrees that a reasonable timeframe should be established for maintaining such records and intends to specify such timeframes as part of the approval order. Accordingly, FDA has modified the regulation to state that records shall be maintained in accordance with the approval order for the HDE.

Section 814.124(a) is amended to allow physicians in emergency situations to administer a HUD prior to obtaining institutional review board (IRB) approval. In such situations, the physician is required to provide written notification, including the identification of the patient involved, the date of use, and the reason for use, to the IRB within 5 days after emergency use. FDA anticipates that five physicians will use HUD's in emergency situations before obtaining approval from an IRB. FDA estimates that notifications under this section will take an average of 1 hour per response.

In addition to the changes required by FDAMA, FDA is amending § 814.104(b)(5) to allow a sponsor who is charging more than $250 per HUD to submit, in lieu of a report by an independent CPA, an attestation by a responsible individual of the organization, verifying that the amount charged does not exceed the device's cost of research, development, fabrication, and distribution. In addition, the amendments to § 814.104(b)(5) waive the requirement for submission of any CPA report or attestation for HUD's for which an HDE applicant is charging $250 or less. FDA anticipates, based on past experience, that 7 of the anticipated 15 HDE holders per year will charge less than $250 per HUD, and thus be exempt from the § 814.104(b)(5) requirement altogether. For the remaining eight HDE holders, FDA anticipates that all will submit attestations in lieu of CPA reports, and estimates that these submissions will require 2 hours to complete.

Description of Respondents: Business or other for profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.104(b)(5)	8	1	8	2	16
814.124(a)	5	1	5	1	5
814.126(b)(1)	15	1	15	120	1,800
Total					1,821

[1] There are no operating and maintenance costs or capital 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
814.126(b)(2)	15	1	15	2	30

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

Dated: July 31, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–21088 Filed 8–6–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0290]

Determination of Regulatory Review Period for Purposes of Patent Extension; Aqueous Aryl Fluorophosphite Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Aqueous Aryl Fluorophosphite Suspension 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 food additive.

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 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