DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0302]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by November 18, 2002.

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: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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

Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act (PDUFA) Products—(OMB Control Number 0910–0429)—Extension

This information collection approval request is for a FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of Prescription Drug User Fee Act (PDUFA) products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (the Modernization Act), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at § 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an end-of-phase 2 meeting and a pre-NDA (new drug application) meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB control number 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.

A. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application. FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the agency as part of an investigational new drug application (IND), NDA, or biological license application (BLA) must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB control number 0910–0014, expires September 30, 2002; and FDA Form 356h, OMB control number 0910–0001, expires March 31, 2005, OMB control number 0910–338, which expires March 31, 2003.

In the guidance document, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the guidance, the agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. Such information includes:

- Information identifying and describing the product;
- The type of meeting being requested;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes from the meeting;
- A preliminary proposed agenda;
- A draft list of questions to be raised at the meeting;
- A list of individuals who will represent the sponsor or applicant at the meeting;
- A list of agency staff requested to be in attendance;
- The approximate date that the information package will be sent to the agency; and
- Suggested dates and times for the meeting.

This information will be used by the agency to determine the utility of the meeting, to identify agency staff necessary to discuss proposed agenda items, and to schedule the meeting.

B. Information Package

A sponsor or applicant submitting an information package to the agency in advance of a formal meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or agency. The agency recommends that information packages generally include:

- Identifying information about the underlying product;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes of the meeting;
- A proposed agenda for the meeting;
- A list of specific questions to be addressed at the meeting;
- A summary of clinical data that will be discussed (as appropriate);
- A summary of preclinical data that will be discussed (as appropriate); and
- Chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The purpose of the information package is to provide agency staff the

opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. Although FDA reviews similar information in the meeting request, the information package should provide updated data that reflect the most current and accurate information available to the sponsor or applicant. The agency finds that reviewing such information is critical to achieving a productive meeting.

The collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to INDs, NDAs, and BLAs and to submit background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an end-of-phase 2 meeting (§ 312.47(b)(1)(ii) and (b)(1)(iv)) and a pre-NDA meeting (§ 312.47(b)(2)).

Description of respondents: A sponsor or applicant for a drug or biological product who requests a formal meeting with the agency regarding the development and review of a PDUFA product.

Burden estimate: Provided in table 1 of this document is an estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance.

C. Request for a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 500 sponsors and applicants (respondents) request approximately 1,253 formal meetings with CDER annually and approximately 176 respondents request approximately 388 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 10 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting.

D. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 450 respondents submitted approximately 1,118 information packages to CDER annually and approximately 155 respondents submitted approximately 341 information packages to CBER annually prior to a formal meeting regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with the guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the agency expects it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the agency.

As stated earlier, the guidance provides information on how the agency will interpret and apply section 119(a) of the Modernization Act, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82). The information collection provisions in § 312.47 concerning end-of-phase 2 meetings and pre-NDA meetings have been approved by OMB (OMB control number 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting for OMB approval these additional estimates.

In the **Federal Register** of July 18, 2002 (67 FR 47383), the agency requested comments on the proposed collections of information. The agency received no comments to the notice.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting Requests and Information Packages	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours per Response	Total Hours
Meeting requests					
CDER	500	2.5	1,250	10	12,500
CBER	176	2.2	387.2	10	3,872
Total					16,372
Information packages					
CDER	450	2.5	1,125	18	20,250
CBER	155	2.2	341	18	6,138
Total					26,388
Meeting requests					16,372
Information packages					26,388
Total					42,760

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

Dated: October 9, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26474 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0315]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices: Humanitarian Use Devices

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.

DATES: Submit written comments on the collection of information by November 18, 2002.

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: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Humanitarian Use Devices—21 CFR Part 814–Subpart H (OMB Control Number 0910–0332)—Extension

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814, subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grants marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making those determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

Description of respondents: Businesses or others for-profit.

FDA estimates the burden of this collection 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
814.102	20	1	20	40	800
814.104	15	1	15	320	4,800
814.106	15	4	60	50	3,000
814.108	12	1	12	80	960
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.124(b)	1	1	1	2	2
814.126(b)(1)	15	1	15	120	1,800
Total					11,368

[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
814.126(b)(2)	15	1	15	2	30

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

Generally, the information requested from the respondents represents an accounting of information already in the possession of the applicant.

In the **Federal Register** of June 26, 1996 (61 FR 33232), FDA published the final rule for HUDs and based its estimates on comments received to the proposed rule (57 FR 60491, December 21, 1992); industry contact; and internal FDA benchmark factors (such as the number of premarket approval applications processed). The numbers generated in the current estimate as shown in tables 1 and 2 of this document are based upon those prior estimates. This is still a relatively new program, and the data acquired from the past several years has remained fairly stable and consistent.