with a working group of the Conference of Radiation Control Program Directors in October 1998 and with the National Mammography Quality Assurance Advisory Committee in November 1998. The guidance has been modified from the original draft proposal to address public comments and to conform to the changes mandated by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998. The major changes include:

1. New guidance for patient communication of results to conform to MQSRA,
2. Reinstatement of the exemption from adverse finding after continuing experience requalification for interpreting physicians and extension to radiologic technologists,
3. Modification of the Automatic Exposure Control mode guidance so that it applies to those modes used clinically at the facility,
4. Revision of the repeat analysis guidance to be consistent with currently accepted practice,
5. Inclusion of the fact that FDA has proposed changes to the collimation requirements,
6. Clarification of what constitutes a major change to the film processor,
7. Further clarification as to what constitutes a ''serious complaint'',
8. Raising inspection finding levels for failure to have a standard operating procedure for infection control and handling consumer complaints, and
9. Raising inspection finding levels for failure to comply with manufacturer's recommendations when performing digital mammography.

II. Significance of Guidance

This guidance represents the agency's current thinking on the final regulations implementing the MQSA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1499) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'', device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'' will be available at ''http://www.fda.gov/cdrh/dmqrp.html''.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance.

Dated: March 10, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–6666 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0296]

Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' This draft guidance document is intended to provide guidance to industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for formal meetings between the agency and sponsors or applicants concerning certain drug products.

DATES: Written comments on the draft guidance may be submitted by May 18, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''Formal Meetings with Sponsors and Applicants for PDUFA Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, or FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to the centers at the following addresses.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' CDER and CBER participate in many meetings each year with sponsors of

investigations and applicants for marketing who seek guidance relating to the development and review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379g(1)) (the Prescription Drug User Fee Act (PDUFA) products). These meetings often represent critical points in the regulatory process. It is essential that FDA maintain procedures for the timely and effective conduct of such meetings.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Pub. L. 105–115) amends section 505(b) of the act (21 U.S.C. 355(b)) and directs FDA to meet with sponsors and applicants, provided certain conditions are met, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim in a new drug application (NDA) submitted under section 505(b) of the act or in a biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (21 U.S.C. 355(b)(4)(B)). Moreover, in conjunction with the reauthorization of PDUFA in November 1997, FDA agreed to specific performance goals for the management of meetings with sponsors and applicants for PDUFA products. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from Donna E. Shalala, Secretary of Health and Human Services, to Senator James M. Jeffords.

The procedures and policies described in this draft guidance document are designed to promote efficient, well-managed meetings between sponsors, applicants, and CDER or CBER. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

FDA participates in formal meetings with various external constituents who seek guidance relating to the development or marketing of drug and biological products. This draft guidance document is the first of two guidances describing CDER's and CBER's procedures for formal meetings. FDA intends to issue additional guidance documents describing CDER's and CBER's procedures for formal meetings with sponsors and applicants for non-PDUFA products (including generic drug products) and for nonapplication related meetings with external constituents.

This draft Level 1 guidance document is being issued consistent with FDA's ''Good Guidance Practices'' (62 FR 8961, February 27, 1997). It represents the agency's current thinking on formal meetings with sponsors and applicants for PDUFA products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before May 18, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (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. 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 comment 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 on respondents, including through the use of automated collection techniques and other forms of information technology, when appropriate.

Title: Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products.

Description: FDA is issuing a draft guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. The draft guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The draft 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 (21 CFR 312.47 and 312.82)).

The draft 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 meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB Control No. 0910–0014). However, the draft guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is providing revised estimates in this notice.

A. Request for a Meeting

Under the draft guidance, a sponsor or applicant interested in meeting with CDER or 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 IND, NDA, or BLA must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under IND's and Form FDA 356h must accompany submissions under NDA's and BLA's. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB Control No. 0910–0014, expires December 31, 1999; and FDA Form 356h, OMB Control No. 0910–0338, expires April 30, 2000.

In the draft 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 data bases. Use of the information in the agency's tracking data bases 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 draft 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 draft guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to IND's, NDA's, and BLA's 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 biologic product who requests a formal meeting with the agency regarding the development and review of a PDUFA product.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance.

Request for a formal meeting. Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that in fiscal year (FY) 1998, 548 sponsors and applicants (respondents) requested formal meetings with CDER and 495 respondents requested formal meetings with CBER regarding the development and review of a PDUFA product. FDA anticipates that the potential number of respondents submitting meeting requests will remain the same, and therefore estimates that the total number of respondents will be 1,043. The agency further estimates that the total annual responses, i.e., the total number of meetings requested per year, will be 1,043, based on data collected from the offices within CDER and CBER. 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 draft 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. Therefore, the agency estimates that sponsors will use 10,430 hours per year requesting formal meetings with CDER and CBER regarding the development and review of PDUFA products.

Information package. Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that in FY 1998, CDER held 527 formal meetings and CBER held 415 formal meetings regarding the review of human drug applications as defined in section 735(1) of the act. FDA anticipates that the potential number of meetings will remain the same; thus, the agency estimates that total annual responses will be 942. As stated previously, it is the current practice for sponsors and applicants to submit information packages to the agency in advance of any such meeting. In FY 1998, 527 respondents submitted information packages to CDER and 415 respondents submitted information packages to CBER prior to the scheduled meetings. FDA anticipates that the potential number of respondents submitting an information package will remain the same; thus, the agency estimates that the total number of respondents will be 942. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package in accordance with this draft 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. Therefore, the agency estimates that respondents will spend 16,856 hours per year submitting information packages to the agency prior to a formal meeting regarding the development and review of a PDUFA product.

As stated earlier, the draft 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 No. 0910–0014). These estimates provide for 100 respondents submitting 100 total annual responses at 24 hours per response, equalling 2,400 total burden hours. Therefore, FDA is subtracting these estimates from the estimates described previously for all formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. Specifically, the agency is subtracting in Table 1 of this document burden estimates for meeting requests and information packages for End-of-Phase 2 meetings and Pre–NDA meetings. This reduces the total estimated burden hours from 27,386 to 24,986.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting Requests and Information Packages	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Meeting Requests					
CDER	548	1	548	10	5,480
CBER	495	1	495	10	4,950
Total					10,430
Information Packages					
CDER	527	1	527	18	9,486
CBER	415	1	415	18	7,470
Total					16,956
Subtotal					27,386
Less 2,400 hours					24,986
TOTAL					24,986

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

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons are requested to send comments on this information collection by April 19, 1999, 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.

Dated: March 9, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6748 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4442–N–07]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The soliciting public comments on the subject proposal.

DATES: Comments are due May 18, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB Control Number and be sent to: Reports Liaison Officer, Office of Policy Development and Research, U.S. Department of Housing and Urban Development, 451 7th Street, SW, Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410. Telephone (202) 708–1537. This is not a toll-free number. Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Ms. Karadbil.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected entities concerning the proposed information collection to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of information to be collected; and (4) Minimize the burden of collection of information on those who are to respond; including through the use of appropriate technology; e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: Notice of Funding Availability and Application Kit for the Hispanic-Serving Institutions Work Study Program (HSI–WSP).

Description of the need for the information and proposed use: The information is being collected to select grantees in this statutorily-created competitive grant program. The information is also being used to monitor the performance of grantees to ensure that they meet statutory and program goals and requirements.

Members of the affected public: Certain Hispanic-serving institutions of higher education: 40 applicants and 15 grantees.

Estimation of the total number of hours needed to prepare the information collection including the number of respondents, frequency of response, and hours of response: Information pursuant to submitting applications will be submitted once. Information pursuant to grantee monitoring requirements will be submitted once a year.

The following chart details the respondent burden on an annual basis: