resources, the composition of the match, and the merit of the match as a criterion in the competitive review. The administratively imposed matching requirement will apply only to new awards and their continuation awards, made under the Fiscal Year 2009 funding opportunity announcements listed in this notice. This Fiscal Year 2009 matching requirement does not represent an addition to the existing matching requirements on awards made under funding opportunity announcements issued in Fiscal Year 2008 or before. The amount and acceptable types of non-Federal resources allowed is not negotiable. However, matching may be provided as direct or indirect costs. The presence and composition of matching funds may be used as a criterion in evaluating the merits of an application during competitive review. Specific information related to the matching requirement and competitive review will be provided in each listed funding opportunity announcement. Unmatched Federal funds will be disallowed. Costs borne by matching contributions are subject to the regulations governing allowability found under 45 CFR 74.23 and 45 CFR 92.24.

The Department of Health and Human Services' Grants Forecast is a database of planned grant opportunities proposed by its various agencies. Each Forecast record contains actual or estimated dates and funding levels for grants that the agency intends to award during the fiscal year. Additional details about ACF planned FY2009 funding opportunity announcements can be found on the Grants Forecast Web site at *https://extranet.acf.hhs.gov/hhsgrantsforecast/.* Published ACF funding opportunity announcements are available on Grants.gov at *http://www.grants.gov* and the ACF Grant Opportunities Web page at *http://www.acf.hhs.gov/grants/open.html.*

FOR FURTHER INFORMATION CONTACT: Karen Shields, Grants Policy Specialist, Office of Administration, Division of Grants Policy, 370 L'Enfant Promenade, SW., 6th Floor East, Washington, DC 20447, or by telephone at 202–401–5112 or *karen.shields@acf.hhs.gov.*

Dated: November 5, 2008

Curtis L. Coy,

Deputy Assistant Secretary for Administration, Administration for Children and Families.

[FR Doc. E8–26889 Filed 11–12–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0556]

Agency Information Collection Activities; Proposed Collection; 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 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

DATES: Submit written or electronic comments on the collection of information by January 12, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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, including each proposed extension of an existing 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 these topics: (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.

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

This information collection approval request is for an FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of 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-New Drug Application meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB Control No. 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.

I. 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 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 No. 0910–0014) and FDA Form 356h (OMB Control No. 0910–0338).

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 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 as follows:

- 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.

II. 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: An estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance is provided in table 1 of this document.

III. Request for a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 907 sponsors and applicants (respondents) request approximately 2,210 formal meetings with CDER annually and approximately 144 respondents request approximately 287 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.

IV. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 774 respondents submitted approximately 1,705 information packages to CDER annually and approximately 120 respondents submitted approximately 198 information packages to CBER annually before 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 No. 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 these additional estimates for OMB approval.

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	907	2.44	2,210	10	22,100
CBER	144	1.99	287	10	2,870
Total					24,970
Information Packages					
CDER	774	2.20	1,705	18	30,690
CBER	120	1.65	198	18	3,564
Total					34,254
Grand Total					59,224

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: November 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27008 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0574]

Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans.'' The interim safety/risk assessment evaluated exposure to melamine and its analogues (cyanuric acid, ammelide and ammeline) in infant formula and other foods to identify, where possible, a level of exposure that would not raise public health concerns. FDA is seeking public comment on the interim safety/risk assessment.

DATES: Comments on the interim safety/risk assessment must be submitted by January 12, 2009.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1057, FAX: 301–436–2973, or e-mail: *Annette.McCarthy@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the interim safety/risk assessment is to identify the level of melamine and melamine-related compounds in food which would not raise public health concerns. On September 11, 2008, FDA learned that melamine may be contained in an infant formula manufactured by a firm in China. As of September 21, 2008, FDA learned that a total of 52,857 cases of nephrolithiasis (and, in some instances, renal failure) had been reported in China linked to consumption of this contaminated powdered formula. There have been approximately 13,000 hospitalizations, and at least 3 deaths have been confirmed to date. The results of an investigation conducted in China indicated that Chinese-produced powdered infant formula was linked to these illnesses; no cases were associated with liquid infant formula. Test results conducted in China on samples of the powdered infant formula showed that they contained a wide range of concentrations (0.1 parts per million (ppm) to greater than 2,500 ppm melamine). In addition, other countries have reported detection of melamine in other product categories, such as confections and beverages.

The interim safety/risk assessment concludes that, based on currently available data and information, there is too much uncertainty for FDA to establish a level of melamine and its analogues in infant formula that does not raise public health concerns. In foods other than infant formula, FDA concludes that levels of melamine and