consider safety and occupational health-related grant applications.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., Health Scientist, NIOSH, CDC, 1600 Clifton Road N.E., Mailstop E–20, Atlanta, Georgia 30333, Telephone: (404) 498–2511, Fax: (404) 498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 16, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–21013 Filed 8–24–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Emergency Contingency Fund for Temporary Assistance for Needy Families (TANF) Programs OFA–100.

OMB No.: 0970–0366.

Description

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Recovery Act), which establishes the Emergency Contingency Fund for State TANF Programs (Emergency Fund) as section 403(c) of the Social Security Act (the Act). This legislation provides up to $5 billion to help States, Territories, and Tribes in fiscal year (FY) 2009 and FY 2010 that have an increase in assistance caseloads and basic assistance expenditures, or in expenditures related to short-term benefits or subsidized employment. The Recovery Act made additional changes to TANF extending supplemental grants through FY 2010, expanding flexibility in the use of TANF funds carried over from one fiscal year to the next, and adding a hold-harmless provision to the caseload reduction credit for States and Territories serving more TANF families.

The Emergency Fund is intended to build upon and renew the principles of work and responsibility that underlie successful welfare reform initiatives. The Emergency Fund provides resources to States, Territories, and Tribes to support work and families during this difficult economic period.

On July 20, 2009 we issued a Program Instruction accompanied by the Emergency Fund Request Form (OFA–100), and instructions for jurisdictions to complete the OFA–100 to apply for emergency funds.

Failure to collect this data would compromise ACF's ability to monitor caseload and expenditure data that must increase in order for jurisdictions to receive awards under the Emergency Fund.

Documentation maintenance on financial reporting for the Emergency Fund is governed by 45 CFR 92.20 and 45 CFR 92.42.

ACF is planning to extend the information collection with the adjustment to the Estimated Annual Burden shown in the table below. Based on our projections for a lower Estimated Annual Burden, we have revised the Number of Respondents to 6 from its previous number of 93 and the Number of Responses per Respondent to 3 from its previous number of 5. Because the Number of Respondents and the Number of Responses per Respondents have been revised, the Estimated Total Burden Hours is now 432, down from its previous number of 11,160.

Respondents

State, Territory, and Tribal agencies administering the Temporary Assistance for Needy Families (TANF) Program that are applying for the Emergency Fund.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF Emergency Fund Request Form, OFA–100	6	5	24	432

Estimated Total Annual Burden Hours: 432.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.*

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–21001 Filed 8–24–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0881]

Draft Guidance for Industry on Self-Identification of Generic Drug Facilities, Sites, and Organizations; 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 ''Self-Identification of Generic Drug Facilities, Sites, and

Organizations.'' On July 9, 2012, the Generic Drug User Fee Amendments of 2012 (GDUFA) (Pub. L. 112–144, Title III) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug facilities, sites, and organizations around the world provide identification information annually to FDA. This guidance is intended to assist industry as it prepares to meet the self-identification requirement. It explains who is required to self-identify, what information must be requested, how the information should be submitted to FDA, and what the penalty is for failure to self-identify.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments concerning the proposed collection of information by October 26, 2012. Submit either electronic or written comments on the draft guidance by October 26, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Jaewon Hong, Center for Drug Evaluation and Research (HFD–300), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–866–405–5367 or 301–796–6707.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Generic Drug User Fee Amendments of 2012 (GDUFA) (Pub. L. 112–144, Title III) was signed into law by the President. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to fund critical and measurable enhancements to FDA's generic drugs program. GDUFA will also significantly improve global supply chain transparency by requiring owners of facilities producing generic drug products and active pharmaceutical ingredients (API) and certain other sites and organizations that support the manufacture or approval of these products to electronically self-identify with FDA and update that information annually.

Self-identification is required for two purposes. First, it is necessary to determine the universe of facilities required to pay user fees. Once the self-identification process has been completed, FDA will determine the fees and publish the amounts in the **Federal Register**. Second, self-identification is a central component of an effort to promote global supply chain transparency. The information provided through self-identification will enable quick, accurate, and reliable surveillance of generic drugs and facilitate inspections and compliance.

This guidance is intended to assist human generic drug facilities, sites, and organizations by describing how FDA will implement the self-identification requirement contained in GDUFA. As required by GDUFA, in the coming weeks FDA will issue a self-identification requirement notice in the **Federal Register**. The notice will explain that human generic drug facilities, sites, and organizations are required to submit identification information electronically to FDA within 60 days. The notice will also list the self-identification information that must be submitted. FDA is issuing this guidance to assist industry as it prepares to meet the self-identification requirement. The guidance explains who is required to self-identify, what information must be requested, how the information should be submitted to FDA, and what the penalty is for failure to self-identify.

To facilitate the implementation of the self-identification requirement in GDUFA, FDA is establishing a new system for the electronic self-identification of generic industry facilities, sites, and organizations. Entities that are required to register and list under section 510 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, and those entities required to self-identify under GDUFA, will submit information separately to the respective systems. Each system will populate its own database to meet unique requirements and deadlines. The new GDUFA system will use the same platform and technical standards already familiar to manufacturers required to register and list.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on self-identification of generic drug facilities, sites, and organizations. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 that 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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the

respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under GDUFA, and as described in the draft guidance, electronic self-identification will be required by all facilities, sites, and organizations involved in the development and manufacturing of generic drugs identified or intended to be identified in an approved or pending FDA generic drug submission. The electronic self-identification requirement applies equally to all domestic and foreign facilities and is independent of the obligation to pay user fees.

Generic drug facilities, sites, and organizations required under GDUFA to self-identify include:

1. Facilities that manufacture, or intend to manufacture, human generic drug APIs or FDFs, or both.

2. Sites and organizations that package the FDF of a human generic drug into the primary container/closure system and label the primary container/closure system.[1]

3. Sites that are identified in a generic drug submission and pursuant to a contract with the applicant remove the drug from a primary container/closure system and subdivide the contents into a different primary container/closure system.

4. Bioequivalence (BE)/bioavailability (BA) sites that are identified in a generic drug submission and conduct clinical BE/BA testing, bioanalytical testing of samples collected from clinical BE/BA testing, and/or in vitro BE testing.

5. Sites that are identified in a generic drug submission and perform testing of one or more attributes or characteristics of the FDF or the API pursuant to a contract with the applicant to satisfy a current good manufacturing practice (CGMP) testing requirement (excludes sites that are testing for research purposes only).

All of the facilities, sites, and organizations listed above are currently required to register and list except for #4.

FDA is establishing a new system for self-identification of generic industry facilities, sites, and organizations. Entities that are required to register and list, and those that are required to self-identify, will submit information to both systems separately. Each system will populate its own database to meet unique requirements and deadlines. Although separate, both systems are built on a common process already familiar to manufacturers required to register and list. This will minimize the cost and effort associated with compliance.

FDA will use the same electronic exchange standards and formats for self-identification that are used in the Drug Registration and Listing System (eDRLS) including XML file formats, which conform to message standards for Structured Product Labeling (SPL). Facilities, sites, and organizations will be able to generate electronic SPL files in the free eSubmitter tool available on FDA's Web site, or other commercially available tools, and submit the files through FDA's Electronic Submissions Gateway. Facilities, sites, and organizations will be required to provide Data Universal Numbering System (D–U–N–S) numbers and Facility Establishment Identifiers (FEI) to enable quick and accurate identification of registrants as well as facilities, sites, and organizations. They will also be required to submit information about the registrant, facility, and SPL file. Requested information will include:

Document Information—
Type of Document
ID Root
Set ID Root
Version number
Effective Time

Registrant Information—
Name
Registrant D–U–N–S Number
Registrant Contact Information
Establishment (Facility) Information—
Name
Establishment Facility D–U–N–S Number
FEI
Physical address
Type of Business Operations
Establishment (Facility) Contact Information

FDA estimates that approximately 2,650 facilities, sites, and organizations (''number of respondents'' in Table 1) will submit the self-identification information set forth above and described in the draft guidance, resulting in approximately 3,000 annual submissions (''total annual responses'' in Table 1). Although there will be one self-identification submission annually by each facility, site, and organization, we rounded the estimate upwards to approximately 3,000 to account for any revisions to the submissions, if needed. These estimates are based on FDA's database of manufacturers in eDRLS and are consistent with conversations between the Agency and representatives of regulated industry during the generic drug user fee negotiations. We also estimate that preparing and submitting this information will take approximately 2.5 hours for each facility (''hours per response'' in Table 1). We base this estimate on the hour burden estimate for submitting drug registration information electronically under eDRLS, as approved by OMB under control number 0910–0045. Most facilities, sites, and organizations are familiar with the eDRLS process and already have the self-identification information available. Entities that are required to register would submit this information separately to the eDRLS system, as approved by OMB under control number 0910–0045.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Generic Drug Facility and Site Electronic Self-Identification (including any revisions to the submission)	2,650	1.13	3,000	2.5	7,500
Total					7,500

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

[1] Sites and organizations that package the FDF of a human generic drug into the primary container/closure system and label the primary container/closure system are considered to be manufacturers, whether or not that packaging is done pursuant to a contract or by the applicant itself.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20946 Filed 8–22–12; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0880]

Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Generic Drug User Fee Amendments of 2012: Questions and Answers.'' The Generic Drug User Fee Amendments of 2012 (GDUFA) is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program. GDUFA also requires that generic drug facilities, sites, and organizations located around the world provide identification information annually to FDA. This guidance is intended to provide answers to common questions from the generic drug industry and other interested parties involved in the development and/or testing of generic drug products regarding the requirements and commitments of GDUFA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 26, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Jaewon Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 866–405–5367 or 301–796–6707.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Generic Drug User Fee Amendments of 2012: Questions and Answers.'' GDUFA (Pub. L. 112–144, Title III) was signed into law by the President on July 9, 2012. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program.

GDUFA establishes fees for abbreviated new drug applications (ANDAs), prior approval supplements (PASs) to ANDAs, and drug master files (DMFs), annual facility fees, and a one-time fee for original ANDAs pending with FDA on October 1, 2012 (backlog fees). Fees will be incurred for ANDAs and PASs submitted on or after October 1, 2012. An application fee will also be incurred the first time a DMF is referenced in an ANDA or PAS submitted on or after October 1, 2012. FDA plans to publish the fee amounts for ANDAs, PASs, DMFs, and the backlog fee in the **Federal Register** on or before October 31, 2012.

The amount of the annual user fees for generic drug facilities will be determined after GDUFA program launch. Under GDUFA, facilities, sites, and organizations are first required to self-identify. Fees will be determined after the self-identification process has been completed, providing FDA information about the number of facilities that will be required to pay user fees. These include facilities manufacturing, or intending to manufacture, active pharmaceutical ingredients of human generic drugs and/or finished dosage form human generic drugs.

This draft guidance is intended to provide answers to common questions from generic drug industry participants and other interested parties involved in the development and/or testing of generic drug products regarding FDA's plans for implementing GDUFA. This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on generic drug user fee amendments of 2012. 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 statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20944 Filed 8–22–12; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0882]

Generic Drug User Fee Amendments of 2012; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a