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. This notice originally had a submission deadline of September 19, 2012. We are republishing the notice to due to incorrect contact information for OMB. Comments already successfully submitted will be given consideration and in the event an individual or organization resubmits comments, there most recent submission will be considered.

DATES: Submit written comments on the collection of information by November 1, 2012.

ADDRESSES: Submit written comments on the collection of information to *OIRA_submission@omb.eop.gov* or by fax to 202.395.5806. Attn: OMB Desk Officer for ACL, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Brianne Burger, 202.618.5525.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. Federal statute and regulation require each State Protection and Advocacy (P&A) System to prepare and solicit public comment on a Statement of Goals and Priorities (SGP) for the P&A for Developmental Disabilities (PADD) program for each coming fiscal year. While the P&A is mandated to protect and advocate under a range of different federally authorized disabilities programs, only the PADD program requires an SGP. Following the required public input for the coming fiscal year, the P&As submit the final version of this SGP to the Administration on Intellectual and Developmental Disabilities (AIDD). AIDD will aggregate the information in the SGPs into a national profile of programmatic emphasis for P&A Systems in the coming year. This aggregation will provide AIDD with a tool for monitoring of the public input requirement. Furthermore, it will provide an overview of program direction, and permit AIDD to track accomplishments against goals/targets, permitting the formulation of technical assistance and compliance with the Government Performance and Results Act of 1993. ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP	57	1	44	2,508

Estimated Total Annual Burden Hours: 2,508.

Dated: September 27, 2012.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2012–24236 Filed 10–1–12; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1010]

Draft Guidance for Industry on Initial Completeness Assessments for Type II Active Pharmaceutical Ingredient Drug Master Files Under the Generic Drug User Fee Amendments of 2012

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Initial Completeness Assessments for Type II API DMFs Under GDUFA.'' Under the Generic Drug User Fee Amendments of 2012 (GDUFA), holders of certain drug master files, namely, Type II active pharmaceutical ingredient (API) drug master files (DMFs) that are referenced in generic drug applications, or in amendments or prior approval supplements to these applications, will be required to undergo an initial completeness assessment in accordance with FDA criteria. This guidance is intended to clarify the criteria FDA will use in the initial completeness assessment.

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 December 3, 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 the 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 20993–0002, 1–866–405–5367 or 301–796–6707.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744B(a)(2)(D)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)(2)(D)(ii)) (FD&C Act), which was added by GDUFA, Title III, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), states that, on or after October 1, 2012, a Type II API DMF will be deemed available for reference in an abbreviated new drug application (ANDA), ANDA amendment, or ANDA prior approval supplement (PAS), if the required fee has been paid *and* if the DMF has not failed an initial completeness assessment ''in accordance with criteria to be published by'' FDA. Any Type II API DMF intended for reference in a generic drug submission for which the fee is paid will undergo an initial completeness assessment. Section 744B(a)(2)(D)(iii) of the FD&C Act requires FDA to make publicly available on its Web site a list of DMF numbers that correspond to DMFs that have successfully undergone an initial completeness assessment in accordance with criteria to be published by FDA and are available for reference.

This list will thus contain DMF numbers for those DMFs for which the fee has been paid and which have successfully undergone the initial completeness assessment. Note that these provisions do not apply to Type II API DMFs that are not intended to be referenced in an ANDA, ANDA amendment, or ANDA PAS.

Fee amounts and the due date for the fee will be announced in a separate **Federal Register** notice or notices.

For DMFs that fail the initial completeness assessment, FDA will issue a letter notifying the holder of the DMF that the DMF is incomplete and identifying missing elements in the DMF that must be addressed. Once the DMF is amended, FDA will re-evaluate it for completeness. This draft guidance describes the criteria that FDA will use in its initial completeness assessment of Type II API DMFs to be referenced in generic drug submissions.

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 initial completeness assessments of Type II API DMFs to be referenced in generic drug submissions. 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: September 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24325 Filed 10–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1006]

Generic Drug Facilities, Sites and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Requirement.

SUMMARY: The Food and Drug Administration (FDA) is notifying generic drug facilities, and certain sites and organizations identified in a generic drug submission, that they must provide identification information to FDA. This information is required to be submitted to the FDA annually under the Generic Drug User Fee Act Amendments of 2012 (GDUFA) included in the Food and Drug Administration Safety and Innovation Act (FDASIA). This notice is intended to help organizations ascertain if they need to self-identify with the FDA, determine what information they are required to submit, and familiarize themselves with the means and format for submitting the required information.

DATES: For fiscal year 2013, identification information must be submitted by December 3, 2012. For each subsequent fiscal year, identification information must be submitted, updated, or reconfirmed on or before June 1 of the preceding fiscal year.

ADDRESSES: Electronic tools for submitting the required information may be found at the following Web sites:

- *eSubmitter tool: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm.*
- *Structured Product Labeling (SPL) Xforms: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm.*

Step-by-step instructions for electronically creating, validating, and submitting self-identification information are available at *www.fda.gov/gdufa.* Technical specifications for self-identification are also available at *www.fda.gov/gdufa.* Once finalized, the file should be transmitted to FDA through the Electronic Submissions Gateway (ESG), FDA's electronic information portal. Information on the ESG is available at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.*

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 20993–0002, 1–866–405–5367 or 301–796–6707.

SUPPLEMENTARY INFORMATION: On July 9, 2012, GDUFA (FDASIA, Title III) (Pub. L. 112–144, Title III) was signed into law by the President. GDUFA requires that generic drug facilities, and certain sites and organizations identified in a generic drug submission, provide identification information annually to FDA. This notice specifies who is required to self-identify, the type of information to be submitted, the means and format for submission of this information, and the penalty for failing to comply. Additional information is contained in the draft guidance for industry entitled ''Self-Identification of Generic Drug Facilities, Sites and Organizations'' available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* This self-identification information will assist in constructing an accurate inventory of facilities, sites and organizations involved in the manufacture of generic drugs. Among other things, the identification information may be used by FDA for purposes including setting fee amounts and targeting inspections.

I. Who is required to self-identify?

The following types of generic industry facilities, sites, and organizations are required to be identified to FDA:

1. Facilities identified, or intended to be identified in at least one generic drug submission that is pending or approved to produce a finished dosage form (FDF) of a human generic drug or an active pharmaceutical ingredient (API) contained in a human generic drug. Thus, facilities engaged in manufacturing or processing a generic API or FDF must be identified. For purposes of self-identification and payment of fees, GDUFA defines API and FDF manufacturers differently from the way they have been defined historically. The GDUFA definitions are included in the draft guidance for industry entitled ''Self-Identification of Generic Drug Facilities, Sites and Organizations,'' available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

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