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 section 6004 of the ACA, manufacturers and ADRs must submit the following drug sample information to FDA each year: (1) The identity and quantity of drug samples requested; (2) the identity and quantity of drug samples distributed; (3) the name, address, professional designation, and signature of any person who makes or signs for the request; and (4) any other category of information determined appropriate by the Secretary. The draft guidance clarifies the specific information that should be submitted under this provision and the manner in which that information should be submitted.

The draft guidance states that FDA's Gateway became available for drug sample reporting under 6004 in March 2012, and that FDA intends to continue the use of the Gateway for this purpose. The Gateway accepts submissions in XML format. Technical specifications for the data type and size for submitting each of the items listed previously may be found in the ACA Industry Submission Specifications User Guide, available at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM297610.pdf.*

The Gateway requests that manufacturers and ADRs provide the following information, which is sufficient to comply with the reporting requirements set forth in section 6004 of the ACA:

- The year the sample was distributed to the provider;
- the type of business (i.e., either manufacturer or distributor);
- the business name of the manufacturer or distributor that distributed the drug sample;
- the trade name and dosage of the drug sample distributed;
- the total quantity of the drug requested by the practitioner during the calendar year;
- the total quantity of the drug distributed to the practitioner during the calendar year;
- the first name, last name, and middle initial of the practitioner;
- the practitioner's designation (i.e., M.D., D.O., P.A., or more);
- the street number, street name, city, state, and ZIP code address of the practitioner;
- an electronic affirmation that a signed written request for drug samples was received by the manufacturer or ADR from the licensed practitioner and is available to FDA upon request;
- an electronic affirmation that a signature of the requesting practitioner, or appropriate designee, acknowledging receipt of drug samples has been received by the manufacturer or ADR and is available to FDA upon request;
- the first name, last name, and middle initial of a practitioner's designee; and
- the address, including street number, street, city, state, and ZIP code of the designee.

Based on the current number of submissions since the enactment of section 6004 of the ACA, we estimate that annually a total of approximately 120 to 250 manufacturers or ADRs (''number of respondents'' in table 1) will submit the drug sample information specified, resulting in approximately 120 to 250 annual submissions (''total annual responses'' in table 1). We also estimate that preparing and submitting this information to FDA will take approximately 500 to 600 hours for each manufacturer or ADR (''hours per response'' in table 1). We base the burden hour estimate on information we obtained from two manufacturers who have submitted the drug sample information since the enactment of section 6004 of the ACA. We are using the upper end of these ranges to calculate the burden in table 1, and the burden hour estimate includes the time that may be needed to submit any followup or additional information to FDA. In addition, for purposes of this notice, FDA assumes that only manufacturers will submit the required information on behalf of all samples distributed, thereby excluding the need for ADRs to do so.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 6004 of the ACA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of drug sample information	250	1	250	600	150,000

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

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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.*

IV. Electronic Access

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

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16238 Filed 7–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0902]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions; Amendments and Easily Correctable Deficiencies Under the Generic Drug User Fee Amendments; 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 ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA.'' The guidance document is intended to assist applicants in preparing to submit to FDA amendments to abbreviated new drug applications (ANDAs) or prior approval supplements (PASs) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), by explaining how the Generic Drug User Fee Amendments of 2012 (GDUFA) performance metric goals apply to these submissions. When finalized, this guidance will replace the December 2001 guidance for industry entitled ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications'' in consideration of the new amendment review tier system and performance goals under 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 September 9, 2014.

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 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *Elizabeth.Giaquinto@fda.hhs.gov* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *stephen.ripley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA.'' On July 9, 2012, GDUFA (Pub. L. 112–144, Title III) was signed into law by the President to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, FDA agreed to certain performance goals and procedures for the review of amendments submitted to original ANDAs and PASs filed on or after October 1, 2014.

This draft guidance describes how FDA intends to classify major amendments, minor amendments, and easily correctable deficiencies (ECDs). Specifically, the draft guidance defines the types of amendments and describes the GDUFA performance metric goals for the amendment tiers, the process for submitting amendments, and dispute resolution procedures regarding amendment classifications.

In accordance with the Commitment Letter, the GDUFA performance metrics described in the draft guidance only apply to amendments to original ANDAs and PASs submitted on or after October 1, 2014, and do not apply to amendments submitted on or after October 1, 2014, that amend original ANDAs or PASs submitted before October 1, 2014.

Elsewhere in this issue of the **Federal Register**, FDA is announcing another draft guidance entitled ''ANDA Submissions—Prior Approval Supplements Under GDUFA,'' which describes FDA's performance metric goals and clarifies how FDA will handle a PAS and amendments to a PAS for an ANDA.

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 02BC;s current thinking on ''ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA.'' 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.96 have been approved under OMB control number 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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

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Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16235 Filed 7–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0901]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions—Prior Approval Supplements Under the Generic Drug User Fee Amendments of 2012; 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 ''ANDA Submissions—Prior Approval