

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.

Postmarketing Safety Reports for Human Drug and Biological Products: Waivers From Electronic Submission Requirements—OMB Control Number 0910-0770—Extension

This information collection supports FDA regulations. In the **Federal Register** of June 10, 2014 (79 FR 33072), FDA published a final rule entitled "Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements." The final rule amended FDA's postmarketing safety reporting regulations for human drug and biological products under 21 CFR parts 310, 314, and 600 and added part 329 to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. Specifically, this includes:

- manufacturers; packers; distributors; applicants with approved new drug applications, abbreviated new drug applications, and biologics licensing applications (BLAs); and those that market prescription drugs for human use without an approved application must submit postmarketing

safety reports to the Agency (§§ 310.305, 314.80, 314.98, and 600.80);

- manufacturers, packers, or distributors whose name appears on the label of nonprescription human drug products marketed without an approved application must report serious adverse events associated with their products (section 760 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379aa)); and

- applicants with approved BLAs must submit biological lot distribution reports to the Agency (§ 600.81).

Under §§ 310.305(e)(2), 314.80(g)(2), 329.100(c)(2), 600.80(h)(2), and 600.81(b)(2), those who are subject to these postmarketing safety reporting requirements may request a waiver from the electronic format requirement. While FDA currently has OMB approval for the collection of postmarketing safety reports,¹ this information collection supports respondents seeking waivers from submitting those reports in electronic format as required by the regulations.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(e)(2)	1	1	1	1	1
314.80(g)(2)	5	1	5	1	5
329.100(c)(2)	1	1	1	1	1
600.80(h)(2)	5	1	5	1	5
600.81(b)(2)	1	1	1	1	1
Total					13

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

In table 1 of this document, we estimate the burden associated with the submission of waiver requests for postmarketing safety reports in electronic format under §§ 310.305(e)(2), 314.80(g)(2), 329.100(c)(2), 600.80(h)(2), and 600.81(b)(2). We expect few waiver requests. We estimate that approximately one manufacturer will request a waiver annually under §§ 310.305(e)(2), 329.100(c)(2), and 600.81(b)(2), and approximately five manufacturers will request a waiver annually under §§ 314.80(g)(2) and 600.80(h)(2). We estimate that each waiver request will take approximately 1 hour to prepare and submit.

Dated: October 24, 2017.
Lauren Silvis,
Chief of Staff.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0880]

Assessing User Fees Under the Generic Drug User Fee Amendments of 2017; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft

¹ FDA currently has OMB approval for submission of postmarketing safety reports under parts 310, 314, and 600. The information collection for parts 310 and 314 is approved under OMB

control numbers 0910-0291 and 0910-0230. The information collection for part 600 is approved under OMB control numbers 0910-0291 and 0910-0308. Submissions required by section 760 of the

FD&C Act have been approved under OMB control number 0910-0636.

guidance for industry entitled “Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.” This draft guidance provides stakeholders information regarding the implementation of the Generic Drug User Fee Amendments of 2017 (GDUFA II) and policies and procedures surrounding its application.

DATES: Submit either electronic or written comments on the guidance December 29, 2017 to ensure that the Agency considers your comment on this draft guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2012-D-0880 for “Assessing User Fees Under the Generic Drug User Fee

Amendments of 2017.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT:

Mehrban Iranshad, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 4145, Silver Spring, MD 20993, 301-796-7900, CDERCollections@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.” GDUFA II (Pub. L. 115-52, Title III) was signed into law by the President on August 18, 2017. GDUFA II continues FDA’s and industry’s goal to improve the public’s access to safe and effective generic drugs and to improve upon the predictability of the review process. GDUFA II extends FDA’s authority to collect user fees from fiscal year (FY) 2018 to FY 2022 and introduces a number of technical revisions that affect what fees are collected and how some fees are collected. GDUFA II authorizes fees for abbreviated new drug applications (ANDAs), drug master files (DMFs), annual facility fees, a one-time fee for original ANDAs pending with FDA on October 1, 2012 (backlog fees), and the Generic Drug Applicant Program Fee (GDUFA Program Fee).

The draft guidance announced in this notice addresses changes in user fee assessments from GDUFA I, user fees incurred by industry under GDUFA II, payment procedures, reconsideration and appeals, and other additional information to assist industry in complying with GDUFA II. FDA will issue separate guidance documents regarding GDUFA II non-user fee requirements and processes.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent the Agency’s current thinking on “Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 guidance refers to collections of information for filling out and submitting Form FDA 3913 (User Fee Payment Refund Request), previously approved under OMB control number 0910-0805, and Form FDA 3914 (User Fee Payment Transfer Request), previously approved under OMB control number 0910-0805.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 25, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-23526 Filed 10-27-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0689]

De Novo Classification Process (Evaluation of Automatic Class III Designation); Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled “De Novo Classification Process (Evaluation of Automatic Class III Designation).” The purpose of this document is to provide guidance on the process for the submission and review of a De Novo classification request (hereafter a “De Novo request”) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), also known as the De Novo classification process. FDA is issuing this guidance to also provide updated recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process. This guidance replaces “New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff,” dated February 19, 1998.

DATES: The announcement of the guidance is published in the **Federal Register** on October 30, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2011-D-0689 for “De Novo Classification Process (Evaluation of Automatic Class III Designation); Guidance for Industry and Food and Drug Administration Staff; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “De Novo Classification Process (Evaluation of Automatic Class III Designation)” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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,