Institutes of Health/National Library of Medicine or a similar source. When providing this information, please provide weblinks to where this information is publicly available. This information may assist in FDA's determination of which SDOs may fulfill the statutory requirements.

Dated: October 25, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23519 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–2008–N–0334]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 requirements for electronic submission of postmarketing safety reports for human drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by December 29, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 29, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 29, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2008–N–0334 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

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.

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.

[FR Doc. 2017–23518 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–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.