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
10.75, Request for review of a scientific dispute	1	4	4	10	40

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

In the next 3 years, CVM anticipates receiving one or fewer requests for review of a scientific dispute per year, on average. We base our estimate on CVM's experience over the past 6 years in handling formal appeals for scientific disputes. The burden of this collection has changed. The number of respondents decreased from two to one annually, the number of responses per respondent remained at four annually, the hours per response remained at 10 annually, and the total number of hours decreased from 80 to 40. This decrease in the total hours is the result of a natural fluctuation in the number of respondents taking advantage of this dispute resolution process.

Dated: February 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02593 Filed 2–8–18; 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; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 12, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0770. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Safety Reports for Human Drug and Biological Products: Waivers From Electronic Submission Requirements

OMB Control Number 0910–0770—Extension

This information collection supports information collection found in 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 (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), of the regulations, 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.

In the **Federal Register** of October 30, 2017 (82 FR 50141), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

We therefore estimate the burden of this collection of information as follows:

[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.

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, 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 only 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 waivers annually under §§ 314.80(g)(2) and 600.80(h)(2). We estimate that each waiver request takes 1 hour to prepare and submit. The burden for this information collection has not increased since the last collection.

Dated: February 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02589 Filed 2–8–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by April 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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