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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. 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

[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.

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.

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