4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3847]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0308. 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.

Adverse Experience Reporting For Licensed Biological Products; and General Records--21 CFR Part 600

OMB Control Number 0910-0308--Extension

This information collection helps support implementation of statutory and regulatory authorities that govern adverse experience reporting. Under the Public Health Service Act (PHS Act) (42 U.S.C. 262), FDA may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to ensure its safe use. Regulations implementing adverse experience reporting (AER) requirements applicable to biological products are codified in part 600 (21 CFR part 600). Regulations applicable to combination products subject to regulations in part 600 are found in part 4 (21 CFR part 4)--Regulation of Combination Products. The collections of information are intended to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to biologics licensed under any provision of section 351 of the PHS Act.

To assist respondents with the reporting provisions of the information collection, FDA has created both paper-based and electronic forms. Information may be submitted electronically through *MEDWATCH* or the *Vaccine Adverse Experience Reporting System* (VAERS). AER reports are filed using the MEDWATCH Form FDA-3500A (approved under OMB control numbers 0910-0291 and 0910-0645) or the VAERS-1. Both versions of the forms and instructions are available from the internet at https://vaers.hhs.gov. The forms may also be downloaded, completed, and submitted to the Agency by mail or facsimile.

For operational efficiency, on March 20, 2023, we requested, and OMB has approved, the addition of burden attributable to provisions set forth in part 4, subpart B, previously included in OMB control number 0910-0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of the combination product is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103. Relatedly, § 4.104 explains how and where to submit reports.

In the *Federal Register* of September 28, 2023 (88 FR 66856), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment regarding our estimate of 28 hours per response for periodic adverse experience reports. The comment suggested we lower that estimate but provided no data or explanation in support of the proposed reduction. While we have therefore made no adjustment in our burden estimate, we encourage further comment regarding a basis for assessing burden for the scope of information collection activity covered by the applicable regulations and associated forms.

Respondents: Respondents to this collection of information are manufacturers of biological products (including blood and blood components) and any person whose name appears on the label of a licensed biological product.

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

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
600.80(c)(1), 600.80(d), and 600.80(e); postmarketing 15-day Alert Reports	109	3,806.95	414,958	1	414,958
600.82; notification of discontinuance or interruption in manufacturing	23	1.435	33	2	66
600.80(c)(2); Periodic Adverse Experience Reports	109	3,697	402,973	28	11,283,244
600.81; distribution reports	172	5.727	985	1	985
600.80(h)(2), 600.81(b)(2), and 600.90; waiver requests	35	1.886	66	1	66
Total					11,699,319

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

Table 2.--Estimated Annual Reporting Burden--Biological Products[1]

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper (in hours)	Total Hours
600.12[2]; Maintenance of Records	131	40.145	5,259	32	168,288
600.12 (b)(2); Recall Records	216	3.4028	735	24	17,640
600.80(c)(1) and 600.80(k); AER Records	109	7,503.95	817,931	1	817,931
Total					1,003,859

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

Table 3.--Estimated Annual Reporting Burden--Combination Products[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondents	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
4.102, 4.103, 4.104, 4.105; Postmarketing Safety Reporting for Combination Products, including associated reports and sharing information with other constituent part applicants	11	18	198	0.35 (21 minutes)	69

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

The burden for this information collection has changed since the last OMB approval. The reporting and recordkeeping burden has increased mostly due to an increase in the number of AER reports submitted to FDA and the associated recordkeeping with these reports. We have also added burden we believe attributable to post marketing safety reporting and attendant recordkeeping and disclosures, as required under part 4, subpart B.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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