4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities: Proposed Collection; 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 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 proposed extension of the collection of information applicable to required adverse experience reporting for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2023-N-3847 for "Adverse Experience Reporting for Licensed Biological Products; and General Records." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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.

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.

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

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

21 CFR Section; Activity	Number of Respondents	Number 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	Number of Recordkeepers	Number 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	Number of Respondents	Number 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: September 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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