Medical Devices; Reports of Corrections and Removals—21 CFR Part 806

OMB Control Number 0910–0359—Revision

This information collection supports implementation of provisions of section 519(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(g)) requiring device manufacturers and importers to report promptly to FDA certain actions concerning device corrections and removals and to maintain associated records. Applicable regulations are found in 21 CFR part 806 and set forth definitions, prescribe format and required content elements for reporting, and identify actions that are exempt from the reporting requirements. The information collected is used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. The information also helps ensure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate.

Reports of corrections and removals may be submitted to FDA via mail, email, or using FDA's Electronic Submission Gateway (ESG). To assist respondents with submitting reports of corrections or removals, we developed a fillable PDF electronic submission template entitled, ''Device Correction/Removal Report for Industry,'' that transmits required data to FDA's Recall Enterprise System. Instructions for the fillable template are provided in pop-up text boxes that appear over each data field. We expect that use of the fillable template will expedite processing of the reports of corrections or removals submitted to FDA.

In the **Federal Register** of April 11, 2023 (88 FR 21677), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part; collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Electronic process setup	517	1	517	3.08	1,592	$25,850
806; Submission of corrections and removals	1,033	1	1,033	10	10,330	
4.102(c)(1)(iii); Submitting correction or removal reports (including any sharing of information with other constituent part applicants as required under 4.103)	20	1	20	10	200	
Total					12,122	25,850

For respondents who submit corrections and removals using the ESG, the operating and maintenance costs associated with this information collection are approximately $50 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be reduced if the respondent has already purchased a verification certificate for other electronic submissions to FDA. This burden may also be reduced if respondents utilize the new PDF template and submit it to the Agency using email, mitigating the need for a digital verification certificate.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR part; collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
806; Records of corrections and removals	93	1	93	10	930
4.105(b); recordkeeping by device-led combination products.	279	1	279	0.5 (30 minutes)	140
Total					1,070

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Figures have been rounded.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate, however we have revised the collection to include the new electronic reporting instrument ''Device Correction/Removal Report for Industry.'' We estimate that 50 percent of submitters will use the ESG to submit the required information. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG. For the purposes of estimating the burden, we assume that all respondents who submit corrections and removals using the electronic process will establish a new WebTrader account and purchase a digital verification certificate.

Dated: August 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17264 Filed 8–10–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; 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 guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.'' This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biosimilar products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This draft guidance for industry revises and replaces the draft guidance of the same name issued in June 2018.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2023 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–2018–D–1922 for ''Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products.'' 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, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993, 301–796–1042, *Sandra.Benton@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.'' This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biosimilar products regulated by CDER or CBER. This draft guidance does not apply to meetings associated with the development of products intended for submission in, or review of, new drug applications or abbreviated new drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355), biologics license applications (BLAs) under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)), or submissions for devices under the FD&C Act. For the purposes of this draft guidance, a formal meeting includes any meeting that is requested by a sponsor or applicant following the procedures provided in this draft guidance and includes meetings conducted in any

format (*i.e.,* in-person, virtual (video conference), teleconference, or written response only). This guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings.

This draft guidance for industry revises and replaces the draft guidance of the same name issued on June 5, 2018 (83 FR 26060). This revision includes:

- Changes to the data expectations in Biosimilar Initial Advisory meeting requests
- Addition of Biological Product Development (BPD) Type 2a meeting
- Changes to when the meeting background package is submitted for BPD Type 4 meeting
- Changes to the description of the available meeting formats
- Addition of an option for a request for clarification

FDA also made certain clarifying and editorial changes. Editorial changes were made primarily for clarification.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 regarding sponsor requests to FDA related to the submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in section 351(a) of the PHS Act and part 601 (21 CFR part 601) relating to the submission of a BLA have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and part 601 relating to the submission of biosimilar applications and biosimilar user fee applications have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17261 Filed 8–10–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2629]

Postmarketing Approaches To Obtain Data on Under-Represented Populations in Clinical Trials; 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 guidance for industry entitled ''Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials.'' The purpose of this draft guidance is to describe FDA requirements and provide recommendations for obtaining safety and effectiveness information on drug and biological products, when appropriate, in the postmarketing setting in historically under-represented patient populations in clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2023 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–2022–D–2629 for ''Postmarketing Approaches to Obtain Data on Under-Represented Populations in Clinical Trials.'' 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, 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