information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
''The Accreditation Scheme for Conformity Assessment (ASCA) Program''.	ASCA Program	0910–0889
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21673 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

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 October 23, 2024.

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 0910–0858. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0858—Extension

This information collection helps support implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 21 U.S.C. 353b), which govern compounding by pharmacies, outsourcing facilities, and other entities. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present risks to patients. FDA's compounding program aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs, while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them. Respondents to the information collection are pharmacies, outsourcing facilities, and other entities.

To assist respondents in complying with statutory requirements, we have issued the following topic-specific guidance documents:

TABLE 1—PUBLISHED GUIDANCE DOCUMENTS REGARDING SECTIONS 503A AND 503B OF THE FD&C ACT

Title	Notice of availability publication date
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities (Radiopharmaceutical Compounding and Repackaging Guidance) (available at *https://www.fda.gov/media/102615/download*).	September 26, 2018 (83 FR 48633).

TABLE 1—PUBLISHED GUIDANCE DOCUMENTS REGARDING SECTIONS 503A AND 503B OF THE FD&C ACT—Continued

Title	Notice of availability publication date
Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities (Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance) (available at *https://www.fda.gov/media/102637/download*).	September 26, 2018 (83 FR 48630).
Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (Repackaging Guidance) (available at *https://www.fda.gov/media/90978/download*).	January 13, 2017 (82 FR 4343).
Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (Biological Products Guidance) (available at *https://www.fda.gov/media/90986/download*).	January 19, 2018 (83 FR 2787).

The guidance documents also describe conditions under which FDA generally does not intend to take enforcement action for violations of the FD&C Act. These guidance documents were issued consistent with FDA's good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance documents communicate FDA's current thinking on the respective topics and include information collection that may result in expenditures of time and effort by respondents. In FDA's notices of availability for the guidance documents, we also solicited public comment under the PRA on the information collection provisions. FDA has developed and maintains a searchable guidance database available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Guidance documents covered by this information collection may be found by choosing ''Center for Drug Evaluation and Research'' from among the FDA Organizations, and by selecting the term ''Compounding'' from among the possible filters.[1]

In the **Federal Register** of June 12, 2024 (89 FR 49880), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this information collection as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities).	2	2	4	3	12
Repackaging Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.A of the Repackaging Guidance) ..	6	2	12	3	36
Total	8		16		48

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

Outsourcing facilities submit their initial and biannual product reports identifying drug products repackaged during the previous 6-month period to FDA via the Agency's electronic Drug Registration and Listing System as explained in the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities and the Repackaging Guidance. We expect to receive no waiver requests from the electronic submission process for initial product reports and semiannual reports.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Recommended activity; guidance section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Radiopharmaceutical Compounding and Repackaging Guidance					
Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference (section III.A of the Radiopharmaceutical Compounding and Repackaging Guidance).	10	25	250	0.05 (3 minutes)	12.5

[1] Guidance documents applicable to animal drug compounding regulated by the Center for Veterinary Medicine would also be returned if no FDA Organization is selected; this information collection covers only those compounding guidance documents issued by the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Recommended activity; guidance section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Biological Products Guidance *					
Maintaining records of testing performed in accordance with Appendix A of the Biological Products Guidance (section III.B of the Biological Products Guidance).	5	30	150	0.083 (5 minutes)	12.5
Total	15		400		25

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

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE [1] [2]

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities).	2	5	10	0.5 (30 minutes)	5
Repackaging Guidance					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.A of the Repackaging Guidance).	6	36	216	1	216
Biological Products Guidance					
Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product (section III.B of the Biological Products Guidance).	15	5	75	0.5 (30 minutes)	37.5
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers for each licensed allergenic extract (section III.C of the Biological Products Guidance).	5	300	1,500	0.5 (30 minutes)	750
Total	28		1,801		1,009

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

For purposes of our analysis, we characterize the burden associated with the time and effort expended on the information collection recommendations discussed in the respective guidance documents as either reporting, recordkeeping, or third-party disclosure activities. We reconfigured the original table by splitting it into three tables to better differentiate between the estimated annual reporting, recordkeeping, and third-party disclosure burden. At the same time, our findings show that compliance with recordkeeping requirements applicable to compounded and repackaged drug products is standard practice in the compounding and selling of these drug products under States' pharmacy laws and other State laws governing recordkeeping by healthcare professionals and healthcare facilities. Therefore, we excluded from our estimate recordkeeping practices discussed in the respective guidance documents we consider usual and customary.

For the Repackaging Guidance, to correct a clerical error, we have adjusted the number of disclosures per respondent from 21 to 36 because each respondent is estimated to average 6 different products and average 6 different strengths, which requires 36 (6 × 6) unique labels per respondent. The initial narrative reflected that each product would come in six different strengths and thus require six unique labels, but due to a clerical error, this information was not correctly included in the table. We also adjusted the number of respondents to six to match the number of respondents designing, testing, and producing labels. In addition, we adjusted the total number of disclosures per respondent to two given the biannual reporting requirement.

For the Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance, a row for biannual product reporting was added to capture product reporting that was inadvertently omitted.

Our estimated burden for the information collection reflects constant respondent numbers. The original numbers were based on the information the program received from product reporting data. We do not have a mechanism in place to determine whether or not these numbers have fluctuated upward or downward; however, based on analogous observations of industry through program experience (some product reports), we believe these numbers are constant. Repackagers who are also registered as outsourcing facilities (OF) are not entity types that are individually regulated as repackagers. They are subsumed in the OF entity type and not easily distinguishable. They may or may not report their repackaging operations.

We are updating the information collection to include burden attendant to reporting and disclosure recommendations found in the Agency guidance documents that was inadvertently omitted in the original information collection due to clerical errors. The burden estimate is adjusted

to reflect a resulting increase of 114 hours and 94 responses annually.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21676 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4146]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program

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 information collection associated with the Agency's Biosimilars User Fee Program.

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 22, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–4146 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program.'' 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, 10A–12M, 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 revision 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