1. ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' at *https://www.fda.gov/media/151712/download.*

2. FDA guidance for industry ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014): *https://www.fda.gov/media/86377/download.*

3. FDA guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (Rev. 7) (February 2020): *https://www.fda.gov/media/135373/download.*

4. FDA guidance for industry ''Process Validation: General Principles and Practices'' (Rev. 1) (January 2011): *https://www.fda.gov/files/drugs/published/Process-Validation-General-Principles-and-Practices.pdf.*

5. CDER MAPP 5015.13: ''Quality Assessment for Products in Expedited Programs'' (December 2022): *https://www.fda.gov/media/162786/download?attachment.*

6. FDA draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (Rev. 1) (September 2023): *https://www.fda.gov/media/172311/download.*

7. CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024): *https://www.fda.gov/media/89155/download.*

8. CBER ''SOPP 8101.1: Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products'' (March 2023).

9. CBER ''SOPP 8212: Breakthrough Therapy Products—Designation and Management'' (August 2023).

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21674 Filed 9–20–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3805]

The Accreditation Scheme for Conformity Assessment Program; Draft Guidances for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; 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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three draft guidance documents for the Accreditation Scheme for Conformity Assessment Program entitled ''The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.'' In accordance with amendments made by the FDA User Fee Reauthorization Act of 2022 (FUFRA), part of the Medical Device User Fee Amendments of 2022 (MDUFA V), FDA was directed to conclude the Pilot Accreditation Scheme for Conformity Assessment Program by the end of fiscal year 2023 and continue to operate the program (hereafter referred to as the ASCA Program) consistent with the amended FD&C Act. FDA is publishing these draft guidance documents which, when finalized, are intended to provide updates to improve the ASCA Program. These draft guidance documents are not final nor for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 22, 2024 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–2019–D–3805 for ''The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation

Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.'' 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)).

Electronic copies of these three guidance documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances. Submit written requests for single hard copies of the draft guidance documents entitled ''The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''; ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''; and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Eric Franca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5500, Silver Spring, MD 20993–0002, 301–796–4505, *ASCA@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has concluded the ASCA pilot phase and is establishing an ongoing ASCA Program, in accordance with amendments made to section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d) by section 2005 of the FDA User Fee Reauthorization Act of 2022, part of the Medical Device User Fee Amendments of 2022. The three final ASCA Pilot guidance documents issued on September 25, 2020, are also being updated to make improvements to the ASCA Program based on lessons learned during ASCA's pilot phase and to convey the commitments stipulated in MDUFA V. These draft guidance updates incorporate feedback received through public meetings and webinars, the docket, stakeholder meetings, communications with participating accreditation bodies and testing laboratories, and lessons learned internally from review staff and ASCA staff during the pilot phase. The updates will also allow FDA to appropriately expand ASCA per MDUFA V commitments and expectations.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the current thinking of FDA on the ASCA Program. 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' ''Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document numbers GUI00017037, GUI00020011, and/or GUI00020012, respectively, and complete title(s) to identify the guidance(s) you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of

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]

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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).