

recommendations on how to provide the relevant information to FDA.

This guidance finalizes the draft guidance of the same title issued on October 6, 2022 (87 FR 60686). FDA considered comments received on the draft guidance as the guidance was finalized, and in response a footnote was added to clarify the potential impact of unsolicited amendments submitted after the prior assessment is granted.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA." 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 final guidance contains no 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 21 CFR 314 have been approved under OMB control number 0910–0001.

## III. Electronic Access

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

Dated: October 9, 2024.

**Eric Flamm,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2024–24104 Filed 10–17–24; 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 FDA Staff; Availability; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the *Federal Register* of September 23, 2024. In the notice of availability, FDA requested comments on three draft guidance documents for industry and FDA staff entitled "The Accreditation Scheme for Conformity Assessment (ASCA) Program; Guidance for Industry, Accreditation Bodies,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 ASCA Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff"; and "Biocompatibility Testing of Medical Devices—Standards Specific Information for the ASCA Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff." The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the document published September 23, 2024 (89 FR 77526). Either electronic or written comments must be submitted by December 23, 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 ASCA Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff"; and "Biocompatibility Testing of Medical Devices—Standards Specific Information for the 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.

**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](mailto: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:** In the **Federal Register** of September 23, 2024, FDA published a notice of availability with a 60-day comment period to request comments on draft guidances for industry and FDA staff 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 ASCA Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff”; and “Biocompatibility Testing of Medical Devices—Standards Specific Information for the ASCA Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.”

The Agency has received a request for an extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 30 days, until December 23, 2024. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

Dated: October 10, 2024.

**Eric Flamm,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2024-24096 Filed 10-17-24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-E-0128]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Wavewriter Alpha Spinal Cord Stimulator System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for WAVEWRITER ALPHA SPINAL CORD STIMULATOR SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by December 17, 2024.

Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 16, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

**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 December 17, 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

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