++ Confirm CHAP's policies with respect to surveys being unannounced.

++ Review CHAP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain CHAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

The April 27, 2020 proposed notice also solicited public comments regarding whether CHAP's requirements met or exceeded the Medicare CfCs for home infusion therapy. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between CHAP's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared CHAP's HIT accreditation requirements and survey process with the Medicare CfCs of part 486, subpart I and the survey and certification process requirements of part 488, subpart L. Our review and evaluation of CHAP's HIT application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, CHAP has completed revising its standards and certification processes in order to meet the condition at:

- Section 486.520(b), to address the requirement of the plan of care must be established by a physician prescribing the type, amount and duration for home infusion therapy.
- Section 486.525(a), to include the required language ''plan of care''.
- Section 488.1010(a)(6)(iv), to revise CHAP's procedures for survey reviews.

B. Term of Approval

As authorized under § 488.1040(a), we reserve the right to conduct onsite observations of accrediting organization operations at any time as part of the ongoing review and continuing oversight of an accrediting organization's performance. Based on the review and observations described in section III. of this final notice, we have determined that CHAP's requirements for HIT meet or exceed our requirements. Therefore, we approve CHAP as a national accreditation organization for HITs that request participation in the Medicare program, effective September 25, 2020 through September 25, 2024.

V. Collection of Information Requirements

This document does not impose information collection and requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 21, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid.

[FR Doc. 2020–21147 Filed 9–24–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3805]

The Accreditation Scheme for Conformity Assessment Pilot Program; 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 final guidance documents for the Accreditation Scheme for Conformity Assessment Pilot Program—specifically, ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot 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) Pilot 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) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff.'' These guidances describe the goals, scope, procedures, and framework for the voluntary ASCA Pilot program, and provide information about two groups of consensus standards within the scope of the pilot program.

DATES: The announcement of these guidances is published in the **Federal Register** on September 25, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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) Pilot Program; Guidances 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) Pilot 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) Pilot 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 guidance documents entitled ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot 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) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''; or, ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot 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 or the Center for Biologics Evaluation and Research, Office of Communication, Outreach, and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20903. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erin Cutts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5554, Silver Spring, MD 20993–0002, 301–796–6307; or Stephen Ripley, 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

The FDA Reauthorization Act of 2017 (FDARA) amended section 514 of the FD&C Act (21 U.S.C. 360d) by adding a new paragraph (d) with the title ''Pilot Accreditation Scheme for Conformity Assessment'' (see Pub. L. 115–52, section 205). The new paragraph 514(d) requires FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized standards. Determinations by testing laboratories so accredited that a device conforms with an eligible standard included as part of the pilot program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories. Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of accreditation of a testing laboratory or a request for additional information regarding a specific device.

Under the ASCA Pilot's conformity assessment scheme, ASCA-recognized accreditation bodies accredit testing laboratories using ASCA program specifications associated with each eligible standard and ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories. ASCA-accredited testing laboratories may conduct testing to provide data used to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts testing under the ASCA Pilot, it provides to the device manufacturer all information listed in the ASCA program specifications, which includes an ASCA summary test report. A device manufacturer that uses an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot can then include a declaration of conformity with any necessary supplemental documentation (*e.g.,* ASCA summary test report) as part of a premarket submission to FDA.

FDA held a public workshop entitled ''Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration—Recognized Standards'' on May 22–23, 2018, to obtain input and recommendations from stakeholders about the ASCA Pilot, including its goals and scope as well as

a suitable framework and procedures to facilitate implementation.

FDA considered comments received on the draft guidance ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program'' that appeared in the **Federal Register** of September 23, 2019 (*https://www.govinfo.gov/content/pkg/FR-2019-09-23/pdf/2019-20543.pdf*). FDA revised the guidance as appropriate in response to the comments. In particular, FDA added clarifications and details regarding the ASCA Pilot and its implementation, including changing terminology to describe whether a testing laboratory or accreditation body is participating in the program; providing additional information on how and when FDA will conduct audits under the ASCA Pilot; and clarifying who is responsible for developing test methods and completing the ASCA summary test report. In addition, FDA added several appendices, including an example declaration of conformity for each set of standards in the program, as well as additional example ASCA summary test reports for biocompatibility testing of medical devices. For ease of reading and organizational purposes, FDA separated the document, issued in draft, into three separate guidance documents for final publication.

- ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff'' describes how the ASCA Pilot was designed and how accreditation bodies, testing laboratories, device manufacturers, and FDA staff participate in the program.
- ''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) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff'' provides information specific to the basic safety and essential performance standards in the ASCA Pilot, including which standards are eligible for inclusion in the program, ASCA program specifications for those standards, and recommended premarket submission contents specific to those standards when testing is conducted by an ASCA-accredited testing laboratory.
- ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff'' provides information specific to the biological evaluation of medical device standards and test methods in the ASCA Pilot, including which standards and test methods are eligible for inclusion in the program, ASCA program specifications for those standards and test methods, and recommended premarket submission contents specific to those standards and test methods when testing is conducted by an ASCA-accredited testing laboratory.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represents the current thinking of FDA on the ''Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program''; ''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) Pilot Program''; and ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.'' They do 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 these guidances 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* These guidance documents are also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot 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) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff;'' or ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot 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 following document numbers to identify the guidance you are requesting.

- Document number 17037 for ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''.
- Document number 20011 for ''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) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''.
- Document number 20012 for ''Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Guidance for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff''.

III. Paperwork Reduction Act of 1995

In the **Federal Register** of September 5, 2019 (84 FR 46737), FDA requested public comment on the collections of information associated with the ASCA Pilot. The information collection and our burden estimate is substantially the same, and is meant to encompass, the information collections proposed in the guidances (OMB control number 0910–0889).

These guidances refer to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB Control No.
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
820	Quality System Regulation	0910–0073
803	Medical Device Reporting	0910–0437
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
58	Good Laboratory Practices	0910–0119
312	Investigational New Drug Application	0910–0014
601	Biologics License Application	0910–0338

Dated: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21234 Filed 9–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1816]

Lavipharm Laboratories, Inc., et al.; Proposal To Withdraw Approval of Five Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of five abbreviated new drug applications (ANDAs) and is announcing an opportunity for the ANDA holders to request a hearing on this proposal. The basis for the proposal is that the ANDA holders have repeatedly failed to file required annual reports for those ANDAs and have failed to satisfy the requirement to have an approved risk evaluation and mitigation strategy (REMS).

DATES: The ANDA holders may submit a request for a hearing by October 26, 2020. Submit all data, information, and analyses upon which the request for a hearing relies November 24, 2020. Submit electronic or written comments by November 24, 2020.

ADDRESSES: The request for a hearing may be submitted by the ANDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.

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.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA–2020–N–1816 ''Lavipharm Laboratories, Inc., et al.; Proposal To Withdraw Approval of Five Abbreviated New Drug Applications; Opportunity for a Hearing.'' The request for a hearing will be placed in the docket and 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.

The ANDA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. 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 any decisions on this matter. 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* or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments 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.*