regulations governing the certification of nonsterile neomycin sulfate powder for prescription compounding (53 FR 12644). Based on its evaluation of the written and oral comments received on the proposed rule (44 FR 44180 (July 27, 1979)), and based on other information, FDA concluded that there was a favorable risk:benefit profile for orally administered neomycin sulfate preparations as adjunctive therapy for preoperative suppression of intestinal bacteria and for the treatment of hepatic coma. However, consistent with the findings published in the proposed rule, FDA concluded in the final rule that the risks of adverse reactions from the use of the product for wound irrigation resulted in systemic absorption and a resultant risk of adverse reactions that significantly outweighed any demonstrated benefits. Accordingly, the final rule amended the antibiotic drug regulations by changing the product name from ''neomycin sulfate for prescription compounding'' to ''neomycin sulfate for compounding oral products'' and by requiring package insert labeling to provide information concerning the appropriate uses of the product and to warn about the risks associated with inappropriate use.

Under docket number FDA–1987–D–0240, FDA proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) withdrawing approval of six antibiotic drug applications and abbreviated antibiotic drug applications (AADAs) [2] for nonsterile neomycin sulfate for prescription compounding products unless the application holders submitted supplemental applications providing for a product name and labeling consistent with the revised name and labeling requirements described in the newly amended antibiotic certification regulations (53 FR 12662).[3] In the document, FDA announced the availability of guideline labeling for nonsterile neomycin sulfate for prescription compounding products that manufacturers could adopt to ensure that their labeling would be consistent with the labeling required by the revised antibiotic certification regulations. The proposed order was based on clinical or other experience, tests, or other scientific data that showed nonsterile neomycin sulfate was unsafe for use except when named ''Neomycin Sulfate for Compounding Oral Products'' and used in accordance with package insert labeling that provides information concerning appropriate uses and that warns about risks associated with inappropriate use. Under section 505 and the regulations promulgated at 21 CFR parts 310 and 314, the holders of the applications were given the opportunity for a hearing to show why approval should not be withdrawn. One application holder, Pharma-Tek, Inc. (Pharma-Tek), requested a hearing to challenge FDA's proposal to withdraw approval of its application, AADA 61–579. On December 6, 1988, FDA announced the withdrawal of approval of five of the six applications for nonsterile neomycin sulfate for prescription compounding for which the holders had not requested a hearing (53 FR 49231). The AADA for neomycin sulfate for prescription compounding, AADA 61–579, held by Pharma-Tek, was not withdrawn at that time because of the sponsor's pending hearing request. Today, this application corresponds to ANDA 061579 held by X-Gen Pharmaceuticals, Inc. (X-Gen).

X-Gen informed FDA by letter dated October 9, 2015, that it was withdrawing the hearing request previously filed on behalf of its predecessor Pharma-Tek concerning ANDA 061579. X-Gen also informed FDA that it waived the opportunity for a hearing and, under 21 CFR 314.150(d), X-Gen permitted the Agency to withdraw approval of ANDA 061579 for neomycin sulfate for prescription compounding.

For the reasons discussed in the document published in the **Federal Register** on April 15, 1988, under docket number FDA–1987–D–0240, the Director of FDA's Center for Drug Evaluation and Research finds that ANDA 061579 was withdrawn from sale for safety and effectiveness reasons (21 CFR 314.161(c)). The Director, under section 505(e) of the FD&C Act and under authority delegated to her by the Commissioner, also finds that new evidence of clinical experience, not contained in ANDA 061579 and not available at the time the application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that nonsterile neomycin sulfate for prescription compounding is not shown to be safe for use under the conditions of use upon the basis of which the application was approved (21 U.S.C. 355(e)). Therefore, approval of ANDA 061579 is hereby withdrawn.

Under 21 CFR 314.161(e) and 314.162(a)(2), FDA will remove ANDA 061579 from the list of drug products with effective approvals published in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations.''

Dated: January 23, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01131 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–P

[2] The terms ''antibiotic drug applications'' and ''abbreviated antibiotic drug applications'' are no longer used. AADAs approved under section 507 of the FD&C Act on or before November 20, 1997, are deemed to have been approved under section 505(j) of the FD&C Act.

[3] This proposed regulatory action was necessary because the antibiotic drug certification regulations did not apply to products with applications in which FDA had approved alternative labeling.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6702]

The Least Burdensome Provisions: Concept and Principles; Guidance for Industry 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 a final guidance entitled ''The Least Burdensome Provisions: Concept and Principles.'' FDA utilizes a least burdensome approach to medical device regulation to eliminate unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. This document describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on February 5, 2019.

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–2017–D–6702 for ''The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration 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.

• 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.gpo.gov/fdsys/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.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''The Least Burdensome Provisions: Concept and Principles'' to the Office of the Center Director, Guidance and Policy Development, 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: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by the Food and Drug Administration Modernization Act of 1997, the FDA Safety and Innovation Act (FDASIA), and the 21st Century Cures Act (Cures Act), includes least burdensome provisions that direct FDA to take a least burdensome approach to medical device evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. The updates to the least burdensome provisions in FDASIA and the Cures Act clarified the original least burdensome provisions and further recognized the role of postmarket activities as they relate to premarket decisions. FDA believes, as a matter of policy, that least burdensome principles should be consistently and widely applied to all activities in the premarket and postmarket settings to remove or reduce unnecessary burdens so that patients can have earlier and continued access to high quality, safe, and effective devices. This guidance, therefore, reflects FDA's belief that least burdensome principles should be applied throughout the medical device total product lifecycle.

For the purposes of this guidance, FDA defines ''least burdensome'' as the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time. This guidance describes the least burdensome guiding principles and recommended approach for FDA staff and industry to ensure consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the FD&C Act.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of December 15, 2017 (82 FR 59623). FDA revised the guidance as appropriate in response to the comments. Among the comments that FDA received were those regarding metrics assessing the application of least burdensome principles and internal training on least burdensome principles. FDA issued a Report to Congress entitled ''Least Burdensome Training Audit'' pursuant to section 513(j) of the FD&C Act (21 U.S.C. 360c(j)), as added by the Cures Act.[1] This report summarizes the mandatory training on least burdensome requirements for device review staff and supervisors and outcome of an audit of such training.

This guidance document replaces the 2002 Least Burdensome Guidance

[1] FDA Report to Congress, ''Least Burdensome Training Audit,'' June 8, 2018, available at *https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM610577.pdf.*

entitled ''The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles'' (October 4, 2002).

II. Significance of Guidance

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 ''The Least Burdensome Provisions: Concept and Principles.'' 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1332 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers 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. 3501–3520). The collections of information in the following FDA regulations, guidance, form, and statutory provision have been approved by OMB as listed in the following table:

21 CFR part or section; guidance; FDA form; or statute	Topic	OMB control No.
820	Quality System Regulation	0910–0073
812	Investigational Device Exemption	0910–0078
807, subpart E	Premarket Notification	0910–0120
860.123	Reclassification Petition	0910–0138
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
806	Medical Devices; Reports of Corrections and Removals	0910–0359
803	Medical Device Reporting	0910–0437
822	Postmarket Surveillance	0910–0449
Form FDA 3670	Adverse Event Reports/MedSun Program	0910–0471
801 and 809	Labeling	0910–0485
''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Waiver	0910–0598
807, subparts A through D	Registration and Listing	0910–0625
807, 812, and 814	Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices.	0910–0741
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
42 U.S.C. 241	Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices.	0910–0769
830	Unique Device Identification System	0910–0720
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01022 Filed 2–4–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than March 7, 2019.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests