states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

OCC, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program (Tribal Home Visiting) to support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively-mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

After the first grant year, Tribal Home Visiting grantees must comply with the requirement to submit an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period, and a final report to the Secretary during the final year of their grant. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their reports. The guidance specifies that grantees must address the following:

- Update on Home Visiting Program Goals and Objectives
- Update on the Implementation of Home Visiting Program in Targeted Community(ies)
- Progress toward Meeting Legislatively Mandated Benchmark Requirements
- Update on Rigorous Evaluation Activities
- Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Update on dissemination activities
- Administration of Home Visiting Program
- Technical Assistance Needs

Previously, the guidance included information about both the annual and the final reports from grantees. This extension request includes updates to the guidance to make it specific to just the annual reports. Guidance specific to the final report will be submitted for review and approval by OMB in the future. A comment period will accompany that request.

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Report to the Secretary	23	1	25	575

Estimated Total Annual Burden Hours: 575.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Title V of the Social Security Act, sections 511(e)(8)(A) and 511(h)(2)(A).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–12464 Filed 6–14–21; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2319]

Evaluation of Study Data Exchange Standards for Submission of Study Data to the Center for Veterinary Medicine; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments on the use of study data exchange standards from persons involved in study conduct, data collection, data management, and submission of animal study data intended to support the approval of new animal drug applications, abbreviated new animal drug applications, or applications for conditional approval.

DATES: Submit either electronic or written comments on the notice by September 13, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 13, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2020–N–2319 for ''Evaluation of Study Data Exchange Standards for Submission of Study Data to the Center for Veterinary Medicine.'' 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: Charles Andres, Center for Veterinary Medicine (HFV–180), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0653, *charles.andres@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

For new animal drug applications (NADAs), the FDA requires full reports of investigations that have been conducted to show a new animal drug is safe and effective for use (section 512(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(b)(1)(A))). Additionally, section 512(n)(1)(E) of the FD&C Act (21 U.S.C. 360b(n)(1)(E)) requires that abbreviated applications for the approval of a new animal drug (ANADAs) contain information to show that the generic new animal drug is bioequivalent to the approved new animal drug. FDA also is authorized to grant conditional approval to certain new animal drugs. An application for conditional approval must contain full reports of investigations that have been conducted to show that the new animal drug is safe and that there is a reasonable expectation of effectiveness. (See section 571(a)(2)(B) of the FD&C Act (21 U.S.C. 360ccc(a)(2)(B)).)[1] In addition to the reports of animal studies conducted to support the safety and effectiveness of a new animal drug, copies of the underlying study data are submitted to FDA's Center for Veterinary Medicine (CVM).

As part of our continued effort to modernize our information technology systems and improve efficiency, we have transitioned to an electronic data format for submission of study data for regulatory review. Currently, CVM does not require or suggest study data exchange standards for such submissions. Study data standards are sets of rules on how particular types of data should be structured, defined, formatted, or exchanged between computer systems. The lack of uniformity of submitted electronic data files and the inconsistent use of terminology across submissions impedes efficiency and complicates our efforts to display, evaluate, and validate the data using advanced review and analysis tools. The use of study data exchange standards would improve the clarity and consistency of our expectations regarding submission of electronic data files. Additionally, the conformance to standardized study data format is now being encouraged and implemented in other parts of the FDA.[2]

Study data exchange standards provide a consistent general framework for organizing study data, including templates for datasets, standard or controlled terminology for variables, and standard calculations for common variables. The Clinical Data Interchange Standards Consortium (CDISC) is an open, multidisciplinary, nonprofit organization that has established worldwide industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trial data and metadata for medical and biopharmaceutical product development.[3] CDISC facilitates the development of study data exchange standards as part of a collaboration involving multiple member organizations, including FDA. Two study data exchange standards developed by CDISC that CVM is exploring for potential use are the Standard for Exchange of Nonclinical Data (SEND), a data model developed to support the exchange of nonclinical tabulated datasets for toxicology studies conducted in animals, and the Study Data Tabulation Model (SDTM), a model for exchange of human clinical study data. FDA accepts both SEND and SDTM study data exchange standards for use in regulatory submissions.

We are inviting comments on the use of study data exchange standards from persons involved in study conduct, data collection, data management, and submission of animal study data

[1] Conditional approval allows a sponsor to begin marketing a new animal drug after demonstrating the safety of the product and that there is a reasonable expectation of effectiveness, while the sponsor continues to collect the evidence of effectiveness needed for the product to receive full approval under section 512 of the FD&C Act (21 U.S.C. 360b) (*i.e.,* substantial evidence of effectiveness). Conditional approval is valid for 1 year and can be renewed by FDA annually for up to a total of 5 years, if the sponsor shows sufficient progress towards demonstrating substantial evidence of effectiveness.

[2] *https://www.fda.gov/industry/fda-resources-data-standards.*

[3] *http://www.cdisc.org.*

intended to support the approval of NADAs, ANADAs, or applications for conditional approval (for example, animal drug sponsor, test facility, developer, vendor, user of electronic data capture (EDC) and data visualization software, or study data quality control (QC) and quality assurance (QA) specialist).

II. Other Issues for Consideration

CVM seeks to continuously enhance review efficiency and interactions with the animal health industry. As part of our continued effort to engage with the animal health industry, we are interested in understanding more about the experiences and familiarity of those involved in animal drug development with the use of data exchange standards. We specifically request public comment regarding the questions below. When submitting comments, it would help us if commenters would identify their animal health industry sector (for example, animal drug sponsor, test facility, developer, vendor, user of EDC and data visualization software, or study data QC and QA specialist). We will consider the comments as we evaluate the potential use of study data exchange standards for animal studies submitted as part of the new animal drug approval process.

1. Which study data exchange standards are you currently using, if any, for the submission of study data to CVM; and which tools do you use to review, analyze, or validate the study data?

2. If study data exchange standards are included as part of your study data management process, when are they incorporated (for example, in protocol development, EDC database and case report form development, post-study processing)?

3. What are the potential benefits or anticipated challenges to the animal health industry of harmonizing CVM's data exchange standards expectations with other FDA Centers' expectations?

4. What can CVM do to help industry to be more prepared for, or to reduce the burden of implementing, the use of study data exchange standards?

5. What other comments do you have regarding the use of study data exchange standards for submission of study data to CVM?

Dated: June 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12503 Filed 6–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0390]

Lederle Laboratories et al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on May 12, 2021. The document announced the withdrawal of approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of June 11, 2021. The document indicated that FDA was withdrawing the approval of ANDA 060164, Nystatin Ointment, held by Lederle Laboratories. However, the document published with an incorrect application number for this product. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, May 12, 2021 (86 FR 26058), appearing on page 26058 in FR Doc. 2021–09980, the following correction is made:

On page 26058, in the first column, in the first line in the table, the application number ''060164'' is corrected to read ''061064''.

Dated: June 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12557 Filed 6–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0493]

Medical Devices; Exemption From Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for the generic device type, powered patient transport, all other powered patient transport. These devices are motorized devices used to mitigate mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs. This device type does not include motorized three-wheeled vehicles or wheelchairs, and is distinct from the device type, powered patient transport, powered patient stairway chair lifts, which is classified separately within the same regulation. FDA is publishing this notice to obtain comments in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by August 16, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 16, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 16, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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