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