automatically be transferred to the grant recipient's Performance Data Form;

- Assisted households, regardless of the type(s) of LIHEAP assistance or funding source, excluding households that only receive nominal payments of $50 or less;
- Assisted households, by type of LIHEAP assistance and funding source, having at least one vulnerable member who is at least 60 years or older, disabled, or 5 years old or younger;
- Assisted households, by type of LIHEAP assistance and funding source, with at least one member age 2 years or under;
- Assisted households, by type of LIHEAP assistance and funding source, with at least one member ages 3 years through 5 years; and
- Assisted households, regardless of the type(s) of LIHEAP assistance or funding source, having at least one member 60 years or older, disabled, or 5 years old or younger.

Indian tribal grant recipients are required to submit data only on the number of households, by funding source, receiving heating, cooling, energy crisis, and/or weatherization benefits.

In FFY 2020, OCS updated the form to allow for the reporting of households served by separate LIHEAP funding types and benefits provided by the following: (1) Funds from regular LIHEAP FFY appropriations acts, including any Continuing Resolutions and final appropriations acts, reallotted prior year funds, and federal LIHEAP funds carried-over to or expended in the current year; (2) supplemental funds from the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136); and (3) funds from any subsequent supplemental LIHEAP appropriations acts. ACF proposes similar changes to the report for FFY 2022, including the addition of lines that allow for the reporting of households served by LIHEAP funds from the American Rescue Plan Act of 2021 (Pub. L. 117–2). OCS has also updated the request to reflect the current number of expected respondents and appropriate reporting dates.

The information is being collected for the Department's annual LIHEAP Report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State governments, tribal governments, U.S. territories, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Assisted Household Report—Long Form	56	1	43	2,408
Assisted Household Report—Short Form	151	1	2	302

Estimated Total Annual Burden Hours: 2,710.

Authority: U.S.C. 8629 and 45 CFR.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–04085 Filed 2–25–22; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4247]

Patient-Focused Drug Development: Methods To Identify What Is Important to Patients; Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; 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 for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' This guidance (Guidance 2) is the second in a series of four methodological guidance documents that FDA committed to develop to describe how to collect and submit information from patients and caregivers to be used for medical product development and regulatory decision making. This guidance finalizes the draft guidance of the same title issued on October 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on February 28, 2022.

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–4247 for ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shannon Cole, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–9208, *Shannon.Cole@fda.hhs.gov,* 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

FDA is announcing the availability of a guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' This guidance (Guidance 2) is the second in a series of four methodological patient-focused drug development guidance documents that FDA committed to develop to describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit information from patients and caregivers to be used for medical product development and regulatory decision making. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform medical product development and regulatory decision making. The purpose of Guidance 2 is to present a range of methods and established best research practices to identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease. In particular, the methods and best practices presented can help elicit relevant information from patients and other stakeholders, such as how their disease affects their daily lives; what they find most troublesome; and the challenges, problems, and burdens of the treatment for the disease.

This guidance finalizes the draft guidance entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients'' issued on October 1, 2019 (84 FR 52114). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include incorporating the definitions of relevant terms within the body of the document instead of as part of a glossary. In addition, editorial changes and methodological clarifications were made to improve clarity.

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 ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' 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

This guidance refers to collections of information from individuals under treatment or clinical examination in connection with research, which are not subject to review by the Office of Management and Budget (OMB) under 5 CFR 1320.3(h)(5). Therefore, clearance by the OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. This guidance also refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The information collections described in this guidance are submitted to FDA to support the medical product's effectiveness and to support claims in approved medical product labeling (see 21 CFR 314.50, 314.126, and 601.2). The information collections have been approved under OMB control numbers 0910–0001 and 0910–0338. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Additional Information

Section 3002 of Title III, Subtitle A, of the 21st Century Cures Act (Pub. L. 114–255) directs FDA to develop patient-focused drug development guidance to address a number of areas including under section 3002(c)(2): Methodological approaches that may be used to develop and identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the

management of the patient's disease. In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*), outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

IV. 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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04152 Filed 2–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) at the sponsor's request because the product is no longer manufactured or marketed.

DATES: The approval is withdrawn as of February 28, 2022.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 093–329 for use of a prolonged-release bolus containing sulfamethazine in cattle because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 093–329, and all supplements and amendments thereto, is hereby withdrawn February 28, 2022.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: February 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03539 Filed 2–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0030]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 30, 2022

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: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065408	Epirubicin Hydrochloride (HCl) Injection, 150 milligrams (mg)/75 milliliters (mL) (2 mg/mL), 10 mg/5 mL (2 mg/mL), 50 mg/25 mL (2 mg/mL), and 200 mg/100 mL (2 mg/mL).	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 065411	Epirubicin HCl Injection, 200 mg/100 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL).	Do.
ANDA 065440	Idarubicin HCl Injection, 1 mg/mL	Do.
ANDA 077790	Fludarabine Phosphate for Injection, 50 mg/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
ANDA 091008	Gabapentin Capsules, 100 mg, 300 mg, and 400 mg	Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, Venus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540.