ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of six 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 17, 2023.

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 065111	Kanamycin Sulfate Injection, Equivalent to (EQ) 500 milligrams (mg) base/2 milliliters (mL) and EQ 1 gram (g) base/3 mL.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 079107	Levetiracetam Solution, 100 mg/mL	Tolmar, Inc., 701 Centre Ave., Fort Collins, CO 80526.
ANDA 201832	Nimodipine Capsules, 30 mg	Sofgen Pharmaceuticals, LCC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180.
ANDA 202418	Lamivudine and Zidovudine Tablets, 150 mg; 300 mg.	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 202743	Azelastine Hydrochloride (HCl), Metered Spray, 0.2055 mg/spray.	Padagis US LLC., U.S. Agent for Padagis Israel Pharmaceuticals Ltd. (formerly known as Perrigo Israel Pharmaceuticals Ltd.), 3940 Quebec Avenue North, Minneapolis, MN 55427.
ANDA 203937	Fludeoxyglucose F18 Injection, 4–500 millicurie (mCi)/mL.	Hot Shots NM, LLC, DBA Midwest Positron Technology, LC, 2017 E Kimberly Rd., Suite C, Davenport IA 52807.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 17, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on April 17, 2023 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05360 Filed 3–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0583]

Agency Information Collection Activities; Proposed Collection; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements contained in regulations governing the use of radioactive drugs for basic informational research.

DATES: Either electronic or written comments on the collection of information must be submitted by May 15, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 15, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2010–N–0583 for ''Radioactive Drug Research Committees.'' 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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Radioactive Drug Research Committees—21 CFR 361.1

OMB Control Number 0910–0053—Extension

This information collection request supports regulations and associated Agency forms. Sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371) establish provisions under which FDA issues regulations governing the use of radioactive drugs for basic scientific research. Specifically, section § 361.1 (21 CFR 361.1) sets forth specific regulations about establishing and composing radioactive drug research committees (RDRCs) and their role in approving and monitoring basic research studies using radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulations and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each RDRC will select a chairman, who will sign all applications, minutes, and reports of the committee. Each committee will meet at least once each quarter in which research activity has been authorized or conducted. Minutes will be kept and will include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC will submit an annual report to FDA. The annual report will include the names and qualifications of the members of, and of any consultants used by, the RDRC, using Form FDA 2914 (Report on Research Use of Radioactive Drugs—Membership Summary). The annual report will also include a summary of each study conducted during the preceding year, using Form FDA 2915 (Report on Research Use of Radioactive Drugs—Study Summary).

We developed the guidance document entitled ''Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application'' (August 2010), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radioactive-drug-research-committee-human-research-without-investigational-new-drug-application,* which provides information to help

determine whether research studies may be conducted under an FDA-approved RDRC, or whether research studies must be conducted under an investigational new drug application. It also offers answers to frequently asked questions on conducting research with radioactive drugs, and provides information on the membership, functions, and reporting requirements of an RDRC approved by FDA. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

Under § 361.1(d)(5), each investigator will obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant or, based on a pregnancy test, be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator will immediately report to the RDRC all adverse effects associated with use of the drug, and the committee will then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under the regulations are also specified and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections, are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on our experience with these reporting and recordkeeping requirements and the number of submissions we received under the regulations over the past 3 years.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§ 361.1(c)(3) reports and (c)(4) approval (Form FDA 2914: Membership Summary) [2].	56	1	56	1	56
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary) [3]	37	10	370	3	1,110
§ 361.1(d)(8) adverse events	10	1	10	0.5 (30 minutes)	5
Total			436		1,171

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094979.pdf.*
[3] *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf.*

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
§ 361.1(c)(2) RDRC	56	4	224	10	2,240
§ 361.1(d)(5) human research subjects	37	10	370	0.75 (45 minutes)	278
Total			594		2,518

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted our estimate for the information collection to reflect an annual decrease of 703 hours and 158 responses since OMB's last approval. We attribute this adjustment to a decrease from 3.5 hours to 3 hours per response for public reporting burden for Form FDA–2915: Study Summary to match the burden hours reflected on the form. In addition, this adjustment is also attributable to the Agency receiving fewer submissions over the last few years.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05357 Filed 3–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that LAMZEDE (velmanase alfa-tycv), approved February 16, 2023, and manufactured by Chiesi Farmaceutici S.p.A., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*