can support the waiver of the in vivo BE requirement for certain drug products.

Following the public consultation period, clarifications were made to the guidance based on the comments received.

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 ''M9 Biopharmaceutics Classification System-Based Biowaivers.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. However, this final guidance refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The following collections of information have been approved under OMB control number 0910–0001:

- Submitting under 21 CFR 314.50 content and format of new drug applications, including the pharmacokinetics and bioavailability sections.
- Submitting under 21 CFR 314.70 postapproval changes.
- Submitting under 21 CFR 314.94 content and format of abbreviated new drug applications.

The collections of information for submitting under 21 CFR 312.23 information about pharmacokinetics and biological disposition of the drug has been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09962 Filed 5–11–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4524]

S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals; International Council for Harmonisation; Guidance for Industry; 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 entitled ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidance recommends international standards for the nonclinical safety studies recommended to support the development of pediatric medicines. The guidance provides a weight of evidence approach to determine when nonclinical toxicity studies may be recommended in juvenile animals. If such studies are recommended, the guidance provides appropriate study designs. The guidance is intended to promote harmonization of recommendations for such studies and should facilitate the timely conduct of pediatric clinical trials and reduce the use of animals in accordance with the 3R (replace/reduce/refine) principles. Tissue engineered products, gene and cellular therapies, and vaccines are excluded from the scope of this guidance. The guidance replaces the draft guidance issued on February 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on May 12, 2021.

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–2018–D–4524 for ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' 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 the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Karen Davis Bruno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6428, Silver Spring, MD 20993–0002, 301–796–1199; 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.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. In the **Federal Register** of February 1, 2019 (84 FR 1161), FDA published a notice announcing the availability of a draft guidance entitled ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines.'' The notice gave interested persons an opportunity to submit comments by April 2, 2019. After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in April 2020.

This guidance finalizes the draft guidance issued on February 1, 2019. The guidance describes a weight of evidence approach to determine when nonclinical toxicity studies may be recommended in juvenile animals to support development of medicines to be used in pediatric patients. If such studies are recommended, the guidance also provides appropriate study designs. The guidance describes study designs as consisting of a core set of endpoints that can be supplemented by additional endpoints depending on the concerns identified in the weight of evidence approach. The guidance also provides guidance on potential approaches for the nonclinical support of drugs that will be developed only for use in pediatric patients or that will be first tested in pediatric patients. The guidance is intended to promote harmonization of recommendations for such studies and should facilitate the timely conduct of pediatric clinical trials and reduce the use of animals in accordance with the 3R (replace/reduce/refine) principles.

The draft guidance was revised based on comments received. The revisions include refinement of the weight of evidence approach and in descriptions of the core and additional endpoints that can be incorporated into juvenile animal studies. The final guidance also includes a new section on data interpretation. The appendices on age-dependent development of organ systems by species and preweaning litter allocation in the rodent were also updated. Additionally, the title of the guidance was updated from ''Nonclinical Safety Testing in Support of Development of Pediatric Medicines'' to ''Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.''

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 ''S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312, pertaining to the submission of nonclinical and preclinical data, including a pediatric clinical development plan, have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119; and the collections of information in FDA's guidance for industry on ''Expedited Programs for Serious Conditions—Drugs and Biologics'' has been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–09964 Filed 5–11–21; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 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 June 11, 2021.

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 060164	Nystatin Ointment	Lederle Laboratories, Division of American Cyanamid Co., P.O. Box 8299, Pearl River, NY 10965.
ANDA 060521	Humatin (paromomycin sulfate) Capsules, Equivalent to (EQ) 250 milligrams (mg)/base.	King Pharmaceuticals, 501 5th St., Bristol, TN 37620.
ANDA 061034	Lincomycin Hydrochloride (HCl)	The Upjohn Co. (formerly Pharmacia and Upjohn Co.), 7000 Portage Rd., Kalamazoo, MI 49001.
ANDA 061652	Oxytetracycline	Parke Davis, 201 Tabor Rd., Morris Plains, NJ 07950.
ANDA 061701	Tetracycline	Wyeth Pharmaceuticals, 1211 Sherwood Ave., Richmond, VA 23220.
ANDA 062032	Erypar (erythromycin stearate) Tablets, EQ 250 mg/base and EQ 500 mg/base.	Parke Davis.
ANDA 076490	Lithium Carbonate Extended-Release Tablets, 450 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 083001	Triamcinolone Acetonide Foam	Lederle Laboratories.
ANDA 084803	Chlorpromazine HCl Tablets, 10 mg	Do.
ANDA 087635	Butalbital; Aspirin; Phenacetin; Caffeine, Tablets	Do.
ANDA 090102	Ranitidine HCl Syrup, EQ 15 mg base/milliliters	Torrent Pharma Inc., 150 Allen Rd., Suite 102, Basking Ridge, NJ 07920.
ANDA 206736	Rifampin for Injection, 600 mg/vial	Watson Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 11, 2021. 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 June 11, 2021 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.