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 ''Q13 Continuous Manufacturing of Drug Substances and Drug Products.'' The guidance was prepared under the auspices of ICH. ICH seeks to achieve 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 enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

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. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and 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 October 14, 2021 (86 FR 57159), FDA published a notice announcing the availability of a draft guidance entitled ''Q13 Continuous Manufacturing of Drug Substances and Drug Products.'' The notice gave interested persons an opportunity to submit comments by December 13, 2021. 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 on November 16, 2022.

This final guidance provides guidance on the development, implementation, operation, and life-cycle management of CM and provides clarification on CM concepts and describes scientific approaches and regulatory considerations specific to CM of drug substances and drug products. This guidance also replaces the draft guidance entitled ''Quality Considerations for Continuous Manufacturing,'' issued on February 27, 2019. Many of the principles in that guidance have been incorporated in the guidance entitled ''Q13 Continuous Manufacturing of Drug Substances and Drug Products,'' rendering the 2019 guidance obsolete.

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 ''Q13 Continuous Manufacturing of Drug Substances and Drug Products.'' 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 relating to the submissions of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submissions of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the submissions of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice have been approved under OMB control number 0910–0139.

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

Dated: February 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04212 Filed 2–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0516]

Mylan Pharmaceuticals Inc., et.al.; Withdrawal of Approval of 11 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 11 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 31, 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 075980	Tramadol Hydrochloride (HCl) Tablets, 50 milligrams (mg).	Mylan Pharmaceuticals Inc., 3711 Collins Ferry Rd., Morgantown, WV 26505.
ANDA 075986	Tramadol HCl Tablets, 50 mg	Do.
ANDA 201510	Pirmella 7/7/7 Tablets, 0.035 mg, 0.035 mg, 0.035 mg; 0.5 mg, 0.75 mg, 1 mg.	Lupin Pharmaceuticals, Inc., U.S. Agent for Lupin Ltd., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202.
ANDA 201512	Pirmella 1/35 Tablets, 0.035 mg; 1 mg	Do.
ANDA 203803	Propafenone HCl, Extended-Release Capsules, 225 mg, 325 mg, and 425 mg.	Mylan Pharmaceuticals Inc.
ANDA 203900	Tacrolimus Injection, Equivalent to (EQ) 5 mg base/milliliters (mL).	Hospira, A Pfizer Company, 275 North Field Dr., Lake Forest, IL 60045.
ANDA 203946	Fludeoxyglucose F18 Injectable, 20–300 millicurie (mCi)/mL.	Essential Isotopes, LLC, 1513 Research Park Dr., Columbia, MO 65211.
ANDA 205923	Caspofungin Acetate Powder, 50 mg/vial, and 70 mg/vial.	Xellia Pharmaceuticals USA, LLC, U.S. Agent for Xellia Pharmaceuticals ApS, 2150 East Lake Cook Rd., Suite 1015, Buffalo Grove, IL 60089.
ANDA 209571	Darifenacin Hydrobromide Extended-Release Tablets, EQ 7.5 mg/base and EQ 15 mg/base.	Xiromed, LLC., U.S. Agent for Xiromed Pharma España, S.L., 180 Park Ave., Suite 101, Florham Park, NJ 07932.
ANDA 211972	Zileuton Extended-Release Tablets, 600 mg	Lupin Pharmaceuticals, Inc.
ANDA 213222	Icatibant Acetate Injectable, EQ 30 mg base/3 mL (EQ 10 mg base/mL).	Glenmark Pharmaceuticals Inc., USA, U.S. Agent for Glenmark Pharmaceuticals Ltd., 750 Corporate Dr., Mahwah, NJ 07430.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 31, 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 March 31, 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: February 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04175 Filed 2–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0487]

Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing publication of a discussion paper providing information for stakeholders and soliciting public comments on a specific area of emerging and advanced manufacturing technologies. The discussion paper presents areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER) scientific and policy experts associated with application of artificial intelligence (AI) to pharmaceutical manufacturing. The discussion paper includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research (CBER) stakeholders.

DATES: Submit either written or electronic comments and information by May 1, 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 1, 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