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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 31, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table.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

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–2023–N–0487 for ''Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments.'' 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: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4162, Silver Spring, MD 20993, 240–402–7930, *Elizabeth.Giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Advanced manufacturing is a term that describes an innovative pharmaceutical manufacturing technology or approach that has the potential to improve the reliability and robustness of the manufacturing process and resilience of the supply chain. Advanced manufacturing can: (1) integrate novel technological approaches, (2) use established techniques in an innovative way, or (3) apply production methods in a new domain where there are no defined best practices. Advanced manufacturing can be used for new or currently marketed large or small molecule drug products.

FDA has recognized and embraced the potential of advanced manufacturing. In 2014, CDER established the Emerging Technology Program (ETP) to work collaboratively with companies to support the use of advanced manufacturing. CDER observed a rapid emergence of advanced manufacturing technologies through the ETP and recognized that regulatory policies and programs may need to evolve to enable timely technological adoption.

The National Academies of Sciences, Engineering, and Medicine issued a 2021 report titled *Innovation in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations,* highlighting innovations in integrated pharmaceutical manufacturing processes. These innovations could have implications for measurement, modeling, and control technologies used in pharmaceutical manufacturing. AI may play a significant role in monitoring and controlling advanced manufacturing processes.

This discussion paper presents areas associated with the application of AI to pharmaceutical manufacturing that FDA has identified for consideration as FDA evaluates our existing risk-based regulatory framework. CDER scientific and policy experts identified these areas from a comprehensive analysis of existing regulatory requirements applicable to the approval of drugs manufactured using AI technologies. The areas of consideration in this discussion paper are those for which FDA would like public feedback.

There are additional areas of consideration not covered within this document, for example, difficulties that could result from ambiguity on how to apply existing regulations to AI or lack of Agency guidance or experience. The areas of consideration presented in this discussion paper focus on drug products that would be marketed under a new drug application (NDA), abbreviated new drug application (ANDA), or biologic license application (BLA). Public feedback will help inform CDER's evaluation of our existing regulatory framework.

While the initial analysis focused on products regulated by CDER, FDA's CBER has also encountered a rapid emergence of advanced manufacturing technologies associated with AI. As such, both CDER and CBER stakeholders are invited to provide feedback on the discussion questions.

II. Requested Information and Comments

Interested persons are invited to provide detailed comments to CDER and CBER on all aspects described in the discussion paper. To facilitate input, FDA has developed a series of questions based on the considerations articulated in the discussion paper. The questions are not meant to be exhaustive, and FDA is also interested in any other pertinent information stakeholders would like to share on this topic. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Dated: February 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04206 Filed 2–28–23; 8:45 am]

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