FDA anticipates that the 27 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. This number has been reduced based on the average number of meeting requests received over the past 3 years. To request this meeting, applicants should compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 270 hours to compile and request a meeting with OS. We have revised the hours per response to be consistent with the meetings information collection for originally regulated products (OMB control number 0910–0731).

Based on the September 2020 order vacating the health warning requirements for cigars and pipe tobacco (set forth in 21 CFR 1143.3 and 1143.5) and remanding the Final Deeming Rule's warning requirements for cigars and pipe tobacco, we have removed the burden associated with this activity. We have included 1 token hour of burden associated with the requirements in part 1143 to acknowledge that the requirement remains in the regulations.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. The total estimated burden for this information collection is 1,285,021 reporting hours and 778 annual responses. Our estimated burden for the information collection reflects an overall decrease of 2,779 hours and a corresponding decrease of 262 responses. We attribute this adjustment to updated information in the number of meeting requests with CTP's Office of Science to discuss investigational plans, the removal of burden for the cigar warning plans, the removal of the small-scale manufacturer reporting, and have therefore revised the estimated burden and number of respondents to the information collection.

Dated: October 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22299 Filed 10–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2316]

Discussion Paper: Distributed Manufacturing and Point-of-Care Manufacturing of Drugs; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; 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 specific areas 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 distributed manufacturing (DM) and point-of-care (POC) manufacturing for drugs, including biological products regulated by CDER and the Center for Biologics Evaluation and Research (CBER). FDA recognizes that regulatory policies and programs may need to evolve to enable the timely adoption of these technologies. The discussion paper includes a series of questions for each technology to stimulate feedback from the public.

DATES: Either electronic or written comments and information on the discussion paper must be submitted by December 13, 2022.

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 December 13, 2022. 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–2022–N–2316 for ''Discussion Paper: Distributed Manufacturing and Point-of-Care Manufacturing of Drugs; 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 general term for an innovative pharmaceutical manufacturing technology or approach that has the potential to improve the reliability and robustness of the manufacturing process and supply chain, and increase timely access to quality medicines for the American public. For the purposes of the discussion paper, all references to drugs include both human drugs and biological products (including those regulated by CBER), unless otherwise specified. 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. Advanced manufacturing can potentially be used for new or existing and large or small molecule drugs.

FDA has recognized and embraced the potential of advanced manufacturing for many years. CDER established the Emerging Technology Program in 2014 to work collaboratively with companies to support the use of advanced manufacturing. CDER has observed a rapid emergence of advanced manufacturing technologies through the Emerging Technology Program and recognizes that regulatory policies and programs may need to evolve to enable the timely adoption of these technologies. The National Academies of Sciences, Engineering, and Medicine issued a 2021 report entitled ''Innovation in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations'', noting potential innovations in integrated, flexible, and distributed manufacturing. These potential innovations include modular approaches to streamline drug development and production, and the deployment and use of highly portable manufacturing units. A range of drug manufacturers have recently engaged CDER through the Emerging Technology Program specifically regarding the development of portable and distributed manufacturing platforms.

CBER established the CBER Advanced Technologies Team in 2019 to promote dialogue, education, and input between CBER and prospective innovators and developers of advanced manufacturing technologies. Through these interactions, CBER has observed interest from manufacturers in the implementation of novel manufacturing approaches for CBER-regulated products. CBER also recognizes the need to consider developing a regulatory framework to facilitate the adoption of these emerging technologies. CBER expects the development of advanced manufacturing technologies associated with DM and POC manufacturing for products that it regulates.

The discussion paper (available on FDA's website at: CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative | FDA) presents areas for consideration and policy development identified by CDER scientific and policy experts associated with DM and POC manufacturing that would be valuable as FDA considers developing a regulatory framework that contemplates these technologies for CDER- and CBER-regulated drug and biological products. For the purposes of the discussion paper, CDER and CBER define DM to be a decentralized manufacturing strategy consisting of a manufacturing platform of manufacturing units deployed to multiple locations; POC manufacturing is defined as a subset of DM that uses manufacturing units distributed to host sites in proximity to patient care (*e.g.,* healthcare facilities). Regulatory areas of consideration include applicable statutory provisions, regulations, and guidance related to quality assessment and inspections that could affect an applicant's ability to comply with the current regulatory framework or FDA's assessment of a marketing application.

II. Requested Information and Comments

Interested persons are invited to provide detailed comments to CDER and CBER (see **ADDRESSES**) on all aspects described in the discussion paper. The discussion paper is available on FDA's website for the FRAME initiative at: CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative | FDA. To facilitate input, FDA has developed a series of questions after each technology described 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. This feedback will help inform the Agency's policy development regarding the technologies described in the discussion paper. FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Dated: October 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22386 Filed 10–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0973]

Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in a New Drug Application, Abbreviated New Drug Application, or Biologics License Application; 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 ''Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA.'' This final guidance is intended to assist original applicants and holders of approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics