Record of Decision (ROD) dated November 7, 2014. This announcement follows the requirements of the National Environmental Policy Act (NEPA) as implemented by the Council on Environmental Quality (CEQ) regulations and HHS environmental procedures.

DATES: The Final SEIS will be available October 14, 2022.

FOR FURTHER INFORMATION CONTACT: Thayra Riley, NEPA Coordinator, Office of Safety, Security, and Asset Management, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H20–4, Atlanta, Georgia 30329. Email: *cdc-roybalga-seis@cdc.gov.* Telephone: 770–488–8170.

SUPPLEMENTARY INFORMATION: In accordance with NEPA as implemented by CEQ regulations (40 CFR 1507.3) and HHS environmental procedures, CDC prepared a Final SEIS to analyze the effects of additional proposed components that were not analyzed in the 2014 Final EIS. The potential impacts of construction and operation of these components on the natural and built environment were evaluated.

Alternatives Considered

CDC analyzed two alternatives in the Final SEIS: The Proposed Action (Alternative 1) and the No Action Alternative. Alternative 1 consists of the construction and operation of a Hospital, Medical, and Infectious Waste Incinerator (HMIWI) in a new laboratory building and the operation of two emergency standby power diesel generators. The construction of a new laboratory was included in the 2014 Final EIS and was not re-evaluated in the SEIS. The No Action Alternative consists of the construction of the new laboratory without the HMIWI and two emergency standby power generators.

The Final SEIS evaluates the environmental impacts that may result from Alternative 1 and the No Action Alternative on the following resource categories: air quality, climate change and sustainability, environmental justice, and hazardous/medical/infectious waste. The Final SEIS identifies measures to mitigate potential adverse impacts.

Public Involvement

On January 28, 2022, CDC published a Notice of Intent to prepare a SEIS in the **Federal Register** (87 FR 4603). CDC announced a Notice of Availability (NOA) of the Draft SEIS on July 8, 2022 (87 FR 40844) and the public comment period ended August 22, 2022. During the public comment period, a virtual public meeting was held on July 27, 2022. Two participants attended the meeting.

CDC received five public comments.

- An individual submitted two comments stating they did not agree with the spending associated with the project.
  - CDC acknowledges the comment.
- A civic organization submitted one comment asking about noise or odors associated with lab operations and the stringency of the Georgia Department of Natural Resources, Environmental Protection Department (EPD) rules for handling, treating, and disposing of infectious waste.
  - CDC's response is that noise and odors were determined not to be issues that needed to be included in the SEIS associated with the addition of a new HMIWI and two new emergency standby power generators. Noise levels will not be an issue and will be controlled/limited to levels below Occupational Safety and Health Administration criteria (60 dBA within 4 feet, which is a normal speaking level). No odors will be released from the new incinerator system during operations. The Georgia EPD rules for handling, treating, and disposing of infectious waste are sufficiently stringent and protective of the environment, workers, and public health. CDC has been operating other incinerators on site and the handling of solid waste, including hazardous and medical waste, will continue to comply with Georgia EPD rules and regulations.
- A community advisory group submitted a request for CDC to present an update on the SEIS during the group's September 20, 2022 meeting.
  - CDC declined the request and provided instructions to submit comments on the docket.
- An individual submitted questions about the air quality modeling and cumulative impact analysis.
  - For the analysis of the addition of the HMIWI and two emergency generators, CDC conducted a quantitative analysis of carbon monoxide based on the methodology used during the 2014 Final EIS. The SEIS states that further analysis of the criteria pollutants and hazardous air pollutants would be conducted to support the updated Title V operating permit that is required due to the addition of the HMIWI. Cumulative impacts for the overall implementation of the Roybal Campus 2025 Master Plan were included in the 2014 Final FEIS. Cumulative impacts were considered in the SEIS Air Quality and climate change analysis. Since there are no impacts to environmental justice and negligible impacts to hazardous, medical, infectious waste, these would not contribute to significant cumulative impacts.

CDC made minor revisions to the SEIS based on these comments. The comments and CDC's responses are included in Appendix A of the Final SEIS.

Availability of the Final SEIS: The Final SEIS is available in the Supplemental Materials tab of the docket found on the Federal eRulemaking Portal: *https://www.regulations.gov,* identified by Docket No. CDC–2022–0014.

The NOA of the Final SEIS has been provided to Federal, State, and local agencies and organizations via mail and electronic mail to the interested parties list. The public is being notified of the availability of the Final SEIS through this **Federal Register** publication and a notice published in *The Atlanta Journal-Constitution.* CDC will finalize a ROD no sooner than November 7, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–22370 Filed 10–13–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0305]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 14, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under

Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0768. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0768—Extension

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Implementing regulations are found in 21 CFR subchapter K (parts 1100 through 1150 (21 CFR parts 1100 through 1150)). This information collection supports the reporting, recordkeeping, and third-party disclosure requirements associated with statutory requirements applicable to tobacco products and set forth in Agency regulations. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as a tobacco product that was not commercially marketed in the United States on February 15, 2007, or a modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. An order under section 910(c)(1)(A)(i) of the FD&C Act is required prior to marketing a new tobacco product. This requirement applies unless the product has been shown to be substantially equivalent to a valid predicate product or is exempt from substantial equivalence (21 CFR 1107.1).

Section 910(b) of the FD&C Act states that a premarket tobacco application (PMTA) (part 1114) shall contain full reports of all investigations of health risks; a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product; a full description of methods of manufacturing and processing (which includes a listing of all manufacturing, packaging, and control sites for the product); an explanation of how the product complies with applicable tobacco product standards; samples of the product and its components; and labeling.

FDA also encourages persons who would like to study their new tobacco product to meet with the Office of Science (OS) in the Center for Tobacco Products (CTP) to discuss their investigational plan. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss agenda items. Details regarding the process for requesting a meeting with OS and how FDA will respond may be found at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products.*

FDA efforts regarding issuance of a final guidance for Harmful and Potentially Harmful Constituent reporting (and later a testing and reporting regulation under section 915 of the FD&C Act) is ongoing, and the guidance document will be issued consistent with our good guidance practice regulations found in 21 CFR 10.115, which provide for public comment at any time.

In the **Federal Register** of April 28, 2022 (87 FR 25280) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (PMTA application) and 21 CFR 25.40 Environmental Assessments	200	3.75	750	1,713	1,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan	27	1	27	10	270
21 CFR part 1143 Cigar Warning Plans	1	1	1	1	1
Total					1,285,021

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

FDA estimates an average burden per respondent of 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. We assume, on average, an additional 213 hours is necessary to prepare an environmental assessment in accordance with the requirements of 21 CFR 25.40, for a total of 1,713 hours per PMTA application. This average represents a wide range of hours that will be required for these applications under different circumstances, with a small number requiring more hours (*e.g.,* as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (*e.g.,* as few as 50 hours for applications for products that are very similar to other new products). A PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 electronic nicotine delivery systems (ENDS) Liquids and 108 ENDS Delivery Systems).

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