Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–13091 Filed 6–16–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Town Hall Meeting on Laboratory Biosafety—Use of Laboratory Instruments

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces a meeting regarding biosafety and laboratory instrumentation.

DATES: The meeting will be held on Friday, June 24, 2022, from 10 a.m. to 3:30 p.m., EDT.

ADDRESSES: This meeting is open to the public through a virtual format, limited only by the webcast lines available. Registration is not required. Visit the CDC Safe Labs website for the meeting webcast at *https://www.cdc.gov/safelabs/biosafety-townhall.html.*

FOR FURTHER INFORMATION CONTACT: Nancy E. Cornish M.D., Center for Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, Georgia 30329–4018; Phone: (404)498–2720; Email: *dlsbiosafety@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of this meeting is to provide an overview and discussion on laboratory biosafety when using laboratory instruments to test human and biologic specimens. Meeting topics are listed in the ''Matters to be Considered'' section of this notice.

Matters to be Considered: The agenda will include presentations and discussions on four topic areas: (1) instrument design and incorporating biosafety; (2) perceived risks to laboratory personnel and impact on testing; (3) independent assessment of risks and instrument design; and (4) a discussion of potential areas of collaboration to address issues discussed during the meeting. There will be prepared presentations, discussions among presenters and panelists, and a period for questions and public comments. Agenda items are subject to change as priorities dictate.

Background: CDC's Division of Laboratory Systems is hosting the town hall meeting in collaboration with clinical and public health laboratory partners, and instrument manufacturers to address clinical laboratory biosafety. The recent publication *Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future* (Cornish NE. et. al. Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future. Clin Microbiol Rev. July 2021, Vol. 34/3 e00126–18) discussed critical gaps in clinical laboratory biosafety, including issues related to the use and disinfection of laboratory instruments. The discussion and feedback generated during the meeting will assist in evaluating current biosafety guidance and identify opportunities for improvement in clinical laboratory biosafety and use of laboratory instrumentation. This meeting is a listening session. Participants may provide individual advice or perspectives. CDC is not seeking consensus advice or recommendations from participants.

Dated: June 14, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–13123 Filed 6–16–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on electronic reporting for outsourcing facilities.

DATES: Submit either electronic or written comments on the collection of information by August 16, 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 August 16, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2015–N–0030 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.'' 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: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Revision

This information collection helps support implementation of sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the Federal Food Drug and Cosmetic Act (FD&C Act), which govern requirements for pharmacy compounding and outsourcing facilities, respectively. For efficiency of Agency operations, we are revising the information collection to include related reporting activities currently approved under OMB control number 0910–0827. Specifically, upon electing and in order to become an outsourcing facility, respondents must register under section 503B of the FD&C Act and submit certain reports and updates to FDA. The information is required to be submitted by electronic means unless otherwise exempt, and prepared in such form and manner as the Secretary of the Department of Health and Human Services may prescribe through regulation or guidance. In the guidance for industry ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' (December 2016) available on our website at *https://www.fda.gov/media/90173/download,* we explain how facilities that elect to register with FDA as outsourcing facilities are to submit drug product reports, consistent with section 503B of the FD&C Act. The guidance document describes who must report and what information must be provided to FDA. The guidance document also explains that drug compounding reports must be submitted in structured product labeling (SPL) format using FDA's electronic submissions system, and discusses the consequences of outsourcing facilities' failure to submit reports.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 503B of the FD&C act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial product reports	3	53	159	0.0833 (5 minutes)	13.25
Waiver request from electronic submission of initial product reports.	1	1	1	1	1
June product reports	75	53	3,975	0.025 (1.5 minutes)	99.375
December product reports	75	53	3,975	0.025 (1.5 minutes)	99.375

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Section 503B of the FD&C act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Waiver request from electronic submission of product reports.	1	1	1	1	1
Total					214

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

Respondents to this collection of information are outsourcing facilities. Based upon our evaluation of the information collection, we have adjusted our estimate downward by 16 hours (from 230 to 214) annually to reflect more recent data. We estimate that each year three outsourcing facilities will submit a product report upon initial registration under section 503B of the FD&C Act. We estimate that twice each year 75 outsourcing facilities will submit a report identifying all human drugs compounded in the facility in the previous 6 months. For the purposes of this estimate, each product's SPL submission is considered a separate product response, and therefore each facility's product report will include multiple product responses. We estimate that each facility will average 53 product responses. We expect each product report will consist of multiple product responses per facility and estimate that preparing and submitting this information electronically may take up to 5 minutes for each initial product response.

Assuming an average of 53 product responses per facility, we estimate that, for semiannual reports, preparing and submitting this information electronically will take 1.5 minutes per product response. Our burden estimate for semiannual product report submissions is lower than for initial product reports because outsourcing facilities can save each product response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing the RootID and version number (both SPL metadata), effective date (to identify the reporting period), and the number of units produced, along with other data as appropriate, to appropriate values for the reporting period. Furthermore, if a product was not compounded during a particular reporting period, no product response would be sent for that product during that reporting period.

We expect to receive no more than one waiver request from the electronic submission process for initial product reports and semiannual reports, and that each waiver request will take 60 minutes to prepare and submit.

Dated: June 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13068 Filed 6–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3662]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 July 18, 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 0910–0584. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR Part 866

OMB Control Number 0910–0584—Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with section 513(a)(1)(B) of the FD&C Act, because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and ''other appropriate actions as the Secretary [of HHS] deems necessary'' (section 513(a)(1)(B) of the FD&C Act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on March 22, 2006 (71 FR 14377), establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification was codified in 21 CFR 866.3332, a regulation that describes the new