DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

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 May 13, 2021.

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 0910–0563. 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.

Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

OMB Control Number 0910–0563—Extension

Section 562 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–1) directs FDA to establish adequate dispute resolution (DR) procedures to ensure appropriate review of scientific controversies between FDA and members of regulated industry, including possible review by a scientific advisory committee. To implement this provision, we amended the general appeal regulation applicable across all FDA components (§ 10.75 (21 CFR 10.75)) to provide for advisory committee review (§ 10.75(b)(2)). At the same time and consistent with the mandates of section 562 of the FD&C Act, we adopted an approach whereby specific implementation procedures regarding scientific controversy associated with review of certain FDA decisions are detailed in center-issued guidance.

Accordingly, we developed the guidance for industry ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.'' We intend that the guidance inform manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes about scientific and technical issues relating to current good manufacturing practice (CGMP).

Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance recommends procedures that we believe encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs, and Center levels and procedures for requesting review by the DR panel. The guidance is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* along with additional information regarding the resolution of scientific disputes at FDA.

We estimate only a nominal burden for the information collection and assume that one manufacturer will submit one request annually for tier-one DR and that it will take manufacturers approximately 30 hours to prepare and submit each tier-one DR request. Since our last request for OMB approval of the information collection, we have received no tier-two DRs.

In the **Federal Register** of December 9, 2020 (85 FR 79186), 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	Total hours
Requests for tier-one DR	1	1	1	30	30

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

Our estimated burden for the information collection reflects a decrease of 38 hours and a decrease of 1 request. This adjustment corresponds to a decrease in the number of submissions we have received over the last few years.

Dated: April 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07549 Filed 4–12–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0318]

Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, National Institute of Allergy and Infectious Diseases, Centers for Disease Control and Prevention, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we), the National Institute of Allergy and Infectious Diseases (NIAID), and the Centers for Disease Control and Prevention (CDC) are announcing the following public workshop entitled ''Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea.'' The purpose of the public workshop is to discuss the nonclinical and clinical pharmacology data and clinical trial design considerations regarding developing antimicrobial drugs for the treatment of gonorrhea.

DATES: The public workshop will be held virtually on April 23, 2021, from 9 a.m. to 5 p.m., Eastern Time. Submit either electronic or written comments on this public workshop by June 1, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in virtual format only.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2021. 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–2021–N–0318 for ''Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea.'' 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: Lori Benner and/or Antoinette Ziolkowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

I. Background

FDA, NIAID, and CDC are announcing a public workshop regarding the development considerations of antimicrobial drugs for the treatment of gonorrhea. As such, discussions will focus on the current state of diagnosis and treatment of gonorrhea and nonclinical and clinical trial design considerations for drug development.

II. Topics for Discussion at the Public Workshop

The workshop will focus on discussing challenges and clinical trial