Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0940]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Rapid Response Surveys

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 October 2, 2023.

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 0910–0500. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Rapid Response Surveys

OMB Control Number 0910–0500—Extension

This generic information collection supports research conducted by FDA, as authorized under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA is requesting extension of OMB approval to conduct rapid response surveys (RRS). Through these surveys, FDA seeks to determine whether a problem impacts the public health and to quickly obtain vital information about risks and interventions. FDA will use the information gathered from these surveys to make quick turnaround decisions about safety problems or risk management solutions so the Agency may take appropriate public health action including dissemination of information as necessary. Participation in these surveys is voluntary.

Respondents may include manufacturers and distributors of biologics, drugs, food, animal food and drugs, dietary supplements, food additives, cosmetics, medical devices, and tobacco products; distributors; sponsors and importers; consumers; healthcare professionals; hospitals; specialized medical facilities (*e.g.,* cardiac surgery, obstetrics/gynecology services, pediatric services, etc.) and other user facilities including nursing homes, ambulatory surgical and outpatient diagnostic and treatment facilities when FDA must quickly determine whether or not a problem impacts the public health. Once FDA understands the need for additional surveillance data to address a potential public health hazard, the appropriate respondents will be identified for each unique RRS.

In the **Federal Register** of April 20, 2023 (88 FR 24423), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment, which was generally supportive of FDA's use of RRS. (Comment) The comment suggested that FDA ''authorize, develop, and implement a mechanism that provides States and the most local level of public health departments immediate notification and access to RRS results when the FDA issues a RRS wholly or partially in their areas of jurisdiction.'' (Response) FDA already has in place mechanisms to share pertinent health information with State, local, and tribal authorities. We currently share aggregated data (without personally identifiable information) of hospital reporting RRS. However, FDA's use of RRS has not recently developed data about potential safety problems or risk management solutions that would require development of a new mechanism for immediate notification and access to RRS results. For example, FDA used a RRS to identify and maintain a list of drugs essential for the care and management of hospitalized patients with COVID–19, particularly for ventilated patients in the intensive care units. FDA used the information to help to identify drugs that may be at risk of a regional or national shortage, and to help ensure these drugs remain available to meet the needs of our nation. FDA also used a RRS to engage stakeholders when developing the food safety surveillance sampling assignments. FDA shared information with key external stakeholders on the hot pepper and cucumber sampling assignments and garnered industry feedback through survey questions to ensure that sample collection is done as effectively and efficiently as possible. Neither of these surveys developed information that would require development of a new mechanism for immediate notification and access to RRS results. The latest update survey data from FDA can be found here: *https://www.fda.gov/science-research/fda-science-forum/fda-covid-19-critical-care-drug-monitoring-survey-portal-ongoing-surveillance-critical-drugs-related.* Please also note that if you or your hospital stakeholders are experiencing a drug shortage and need assistance on how to obtain supply, please refer to the information at *Drugshortages@fda.hhs.gov.* FDA Drug Shortage Staff responds to all reports received on a daily basis.

FDA estimates 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
FDA Rapid Response Surveys	10,000	1	10,000	0.5 (30 minutes)	5,000

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

We estimate that each rapid response survey will take no more than 30 minutes to complete.

Based on a review of the information collection since our last request, we have adjusted our burden estimate which has resulted in a decrease to the currently approved burden. We now estimate one response per respondent which results in a decrease in overall burden of 25,000 hours.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3136]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 the information collection provisions of the dispute resolution procedures for science-based decisions on products regulated by the Center for Veterinary Medicine (CVM).

DATES: Either electronic or written comments on the collection of information must be submitted by October 30, 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 October 30, 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–3136 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine.'' 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://*