Dated: June 9, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–12837 Filed 6–14–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Cooperative Agreement To Fund India Council of Medical Research (IMCR) and ICMR Institutions: National Institute of Virology (NIV), Pune and National Institute of Epidemiology (NIE), Chennai

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces three (3) separate awards within the government of India to include the Indian Council of Medical Research (ICMR) New Delhi, National Institute of Virology (NIV) and National Institute of Epidemiology (NIE). For ICMR New Delhi, the award is for approximately $8,165,0000 with an expected total funding of approximately $24,495,000. For NIV, the award is for approximately $8,165,0000 with an expected total funding of approximately $24,495,000. For NIE, the award is for approximately $8,165,0000 with an expected total funding of approximately $24,495,000. The total 5-year period amount for the three recipients is $122,475,000. The awards will accelerate progress toward an India safe and secure from infectious disease threats through ICMR institutions' focus on emerging and re-emerging pathogens, including detecting, and controlling zoonotic disease outbreaks through a One Health approach; evaluating vaccine safety monitoring systems; capacitating the public health workforce in field epidemiology and outbreak response; and combating antimicrobial resistance.

DATES: The period for these awards will be September 30, 2022, through September 29, 2027.

FOR FURTHER INFORMATION CONTACT: Shana Eatman, Centers for Disease Control and Prevention, 1825 Century Center, MS V18–3, Atlanta, GA 30345, Telephone: 770–488–3933, E-Mail: *DGHPNOFOs@cdc.gov.*

SUPPLEMENTARY INFORMATION: The single-source awards will continue support to strengthening cooperation with and capacity of the India Council of Medical Research (ICMR) institutions to prevent avoidable epidemics, early detection of disease threats, and rapid and effective response.

India Council of Medical Research is in a unique position to conduct this work, as it was originally established as an apex body for the formulation, coordination, and promotion of biomedical research in India, and has taken up most of the laboratory-based surveillance of infectious diseases in recent years. Eligibility for funding is limited to the ICMR, New Delhi and ICMR institutions including the National Institute of Virology (NIV), Pune and the National Institute of Epidemiology (NIE), Chennai. ICMR is the apex governing body for the numerous national level institutes which are centres for excellence and reference in specific scientific area for India, namely National Institute of Virology, National Institute of Epidemiology, and several others. These institutions are mandated by the Ministry of Health of Family Health and Welfare (MoHFW) to provide oversight for laboratory confirmation of priority pathogens in India in a tiered manner as well as collate and analyze surveillance data for public health actions and work closely with the state governments where these institutes are located.

Summary of the Award

Recipient: India Council of Medical Research (IMCR), New Delhi and ICMR institutions: National Institute of Virology (NIV), Pune and National Institute of Epidemiology (NIE), Chennai.

Purpose of the Award: The purpose of these awards is to accelerate progress toward an India safe and secure from infectious disease threats through ICMR institutions' focus on emerging and re-emerging pathogens, including detecting, and controlling zoonotic disease outbreaks through a One Health approach; evaluating vaccine safety monitoring systems; capacitating the public health workforce in field epidemiology and outbreak response; and combating antimicrobial resistance. These GHS strategies will result in outcomes that will strengthen the Indian public health system; decrease morbidity and mortality; and improve pandemic and epidemic preparedness and response.

Amount of Award: $8,165,000 in Federal Fiscal Year (FFY) 2022 funds per institution, with a total estimated $122,475,0000 for the 5-year period of performance, subject to availability of funds. Please note, the NOFO funding strategy is as follows: $660,000 for Core Component 1, and $7,505,000 in Approved but Unfunded (ABU) Components for each recipient.

Authority: This program is authorized under Section 307 of the Public Health Service Act [42 U.S.C. 242*l*] and Section 301(a) [42 U.S.C. 241(a)] of the Public Health Service Act.

Period of Performance: September 30, 2022, through September 29, 2027.

Dated: June 9, 2022.

Terrance Perry,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–12850 Filed 6–14–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Health Service Act (PHS), Delegation of Authority

Notice is hereby given that I have delegated to the Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), without authority to redelegate, all authorities vested in the Secretary, under Sections 2695G–2695I, Title XXVI of the PHS Act (42 U.S.C. 300ff–138–300ff–140), as amended. This may not be redelegated.

This delegation is effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by you or your subordinates which involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: June 8, 2022.

Xavier Becerra,

Secretary.

[FR Doc. 2022–12835 Filed 6–14–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0013]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 15, 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 0910–0773. 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.

Sanitary Transportation of Human and Animal Food—21 CFR Part 1, Subpart O

OMB Control Number 0910–0773—Extension

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. The regulations are intended to focus on preventing food safety problems throughout the food chain and were issued under the Sanitary Food Transportation Act of 2005 (2005 SFTA), and the FDA Food Safety Modernization Act, enacted in 2011. The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), in part, by creating section 416 (21 U.S.C. 350e), which directs us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416 of the FD&C Act also directs that we prescribe appropriate human and animal food transportation practice requirements relating to: (1) sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping.

In addition, the 2005 SFTA created section 402(i) of the FD&C Act (21 U.S.C. 342(i)), which provides that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated and section 301(hh) of the FD&C Act (21 U.S.C. 331(hh)), which prohibits the failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the regulations issued under section 416 of the FD&C Act.

The 2005 SFTA also amended section 703 of the FD&C Act (21 U.S.C. 373) by providing that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416 of the FD&C Act.

Accordingly, we issued regulations in 21 CFR part 1, subpart O (21 CFR 1.900 through 1.934) that establish requirements for the sanitary transportation of human and animal food, as well as prescribe procedures for respondents who wish to request a waiver for any requirement. For additional information regarding Agency implementation of the 2005 SFTA, visit our website at *https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/sanitation-transportation-guidance-documents-regulatory-information.*

In the **Federal Register** of February 24, 2022 (87 FR 10369), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the information collection topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.912; Record retention	1,502,032	1	1,502,032	0.083 (5 minutes)	124,669

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

We estimate an annual recordkeeping burden of 124,669, which assumes 1,502,032 workers will spend an average of 5 minutes on activities related to the record retention requirements under § 1.912. We expect these activities will likely include documenting procedures and training, as well as sanitary transportation operations and specification requirements.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.914; Waiver petitions	2	1	2	24	48

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

We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1.908; Disclosure of sanitary specifications; operating temperature conditions.	226	1	226	0.5833 (~35 minutes).	132

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

Finally, we estimate an annual third-party disclosure burden of 132 hours, assuming each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under § 1.908.

Based on an evaluation of the information collection, we have made no adjustments to our burden estimate.

Dated: June 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12914 Filed 6–14–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0705]

Q9(R1) Quality Risk Management; International Council for Harmonisation; Draft 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 draft guidance for industry entitled ''Q9(R1) Quality Risk Management.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The current Q9 guideline published in 2006 provides a common, harmonized framework for Quality Risk Management (QRM) that can enable more effective and consistent risk-based decisions, both by regulators and industry, regarding the quality of drug substances and drug products across the product lifecycle. This draft guidance is a targeted revision that addresses four areas for improvement, including high levels of subjectivity in risk assessments and in QRM outputs; product availability risks; lack of understanding as to what constitutes formality in QRM work; and lack of clarity on risk-based decision-making. The revisions are intended to update the original Q9 guideline based on implementation experience to promote improved lifecycle management of hazards and prevent defects, recalls, and shortages.

DATES: Submit either electronic or written comments on the draft guidance by July 15, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–D–0705 for ''Q9(R1) Quality Risk Management.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' are 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