

availability of funding for grants and cooperative agreements is announced through a Notice of Funding Opportunity (NOFO). CDC awards up to 100 new, non-research NOFOs each year (each funded for one to five years). These awards may have only a few funded recipients or more than 50 (such as when a CDC program provides funding to all states and territories).

CDC programs develop logic models for each NOFO, describing the key programmatic strategies and activities and the short/medium/long-term outcomes funded recipients are expected to achieve during their period of performance. Programs develop performance measures customized to a NOFO-specific public health initiative to assess actions prescribed by the logic model with the immediate goal of monitoring progress and the long-term goal of improving performance.

Monitoring and reporting of program performance is required of any non-federal entity receiving federal funds under 45 CFR 75.342 which states; “the non-Federal entity must monitor its activities under Federal awards to assure compliance with applicable Federal requirements and performance expectations are being achieved”. Under this requested approval, CDC programs customize a sample “Performance Measure Technical Specification Instrument” and a sample “Performance Measure Reporting Instrument” to measure, at the local level, the desired public health outcomes of a particular public health initiative, in compliance with the Paperwork Reduction Act

(PRA). Individual collection requests submitted under this Generic approval will include the tailored forms and a supplementary template. CDC programs developing new, non-research NOFOs are eligible to participate.

Currently three CDC programs have received OMB approval to collect performance measure data using the 0920–1282 Generic Information Collection. Two additional programs are in final CDC clearance for submitting their Generic ICR (GenIC) requests and three programs are actively developing applications. As CDC programs begin to normalize operations following the COVID–19 pandemic, numerous other CDC programs have showed strong interest in participating in the Performance Measures Project (PMP) when: (1) they develop new NOFOs or; (2) transition current performance measure data collection from the HHS Public Health Emergency (PHE) PRA waiver for Coronavirus Disease 2019 [COVID–19] to the PMP GenIC for ongoing performance data collection. This revision is requested to allow participating CDC programs to continue performance measure data collection through the remaining approval period and for additional programs to use the GenIC for future performance measure data collection.

This revision reflects expanded technical assistance that the Program Performance and Evaluation Office (PPEO) provides to CDC programs. CDC program eligibility to participate in PMP will be expanded as follows:

- (1) Given the recent increase in grants and other funding mechanisms used at CDC to enhance programmatic flexibility, PMP eligibility will expand to include all available funding mechanisms for eligible programs.
- (2) PPEO is providing increasing technical assistance to international programs. Eligibility will expand to include both domestic and international programs.
- (3) Many CDC programs are operating under the 21st Century Cures Act PHE PRA COVID–19 Emergency Waiver. This PHE PRA Waiver is likely to be terminated in 2022. PMP will prioritize transitioning CDC program performance measure data collection from the PHE PRA Waiver to PMP.
- (4) Some CDC programs are developing common performance metrics across multiple public health initiatives. PMP will prioritize cross-NOFO collaboration with these programs to increase efficiency.
- (5) As programs transition back to normal function after the COVID–19 pandemic, there has been increased interest in PMP. The revision will increase the number of programs that may participate from 25 Programs to 40, resulting in an increase of estimated annual burden hours from 35,000 to 56,000.
- CDC requests OMB approval for an estimated 56,000 annual burden hours. Participation of respondents is voluntary. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Recipients of CDC funds for public health initiatives.	Performance Measures Project Information Collection Tool.	1400	1	40	56,000
Total	56,000

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Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.*
[FR Doc. 2022–15767 Filed 7–22–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–N–1112; FDA–2018–N–4465; FDA–2014–N–1960; FDA–2018–N–4428; and FDA–2018–N–3353]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and

expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/>

PRAMain. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitation Program	0910-0021	6/30/2025
Administrative Detention and Banned Medical Devices	0910-0114	6/30/2025
MedWatch: The Food and Drug Administration Safety Information and Adverse Event Reporting Program	0910-0291	6/30/2025
Medicated Feed Mill License Application—21 CFR Part 515	0910-0337	6/30/2025
Antimicrobial Animal Drug Distribution Reports and Recordkeeping	0910-0659	6/30/2025

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-15827 Filed 7-22-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2014-N-0801 and FDA-2021-N-0336]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork

Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Export Notification and Recordkeeping Requirements	0910-0482	6/30/2025
Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim "Healthy" on Packaged Food	0910-0905	6/30/2025

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-15822 Filed 7-22-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1548]

Failure To Respond to an Abbreviated New Drug Application Complete Response Letter Within the Regulatory Timeframe; 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 final guidance for industry entitled "Failure To Respond to an ANDA Complete

Response Letter Within the Regulatory Timeframe." This guidance is intended to assist applicants in responding to complete response letters (CRLs) to abbreviated new drug applications (ANDAs) submitted to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance provides information and recommendations regarding potential courses of action for an ANDA applicant after issuance of a CRL as well as the actions that FDA may take if the applicant fails to respond to a CRL. In addition, this guidance recommends information an applicant may submit in its request for an extension to respond to a CRL as well as a non-exhaustive list of factors that FDA generally intends to consider in determining whether such a request is