

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.

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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:

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, PRASStaff@fda.hhs.gov.

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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.

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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