transaction information, the transaction history (when applicable), and transaction statement (T3) to the subsequent purchaser, providing relevant transaction information, transaction history, and transaction statement upon a request for information from FDA or other appropriate Federal or State officials if a recall or investigation of suspect or illegitimate product occurs, and, after the Statutory Date, facilitating the gathering of information necessary to produce the transaction information for each transaction [1] going back to the manufacturer at an authorized trading partner's request, or at the request of FDA or other appropriate Federal or State officials; and (2) capturing and maintaining transaction information, transaction history, and transaction statements for each transaction for not less than 6 years after the transaction. Product identification activities include the requirement that manufacturers and repackagers affix or imprint a product identifier to each package and homogeneous case of products that they intend to be introduced in a transaction into commerce and that they maintain product identifier information for each package and homogeneous case of product for not less than 6 years.

Verification Activities

Verification activities include: (1) coordinating with other trading partners during an investigation of a suspect product to determine whether the product is illegitimate; (2) for manufacturers and repackagers, responding to trading partners' requests for verification of product identifiers; (3) maintaining records of suspect product investigations and disposition of illegitimate product for not less than 6 years; (4) identifying suspect product; (5) quarantining suspect and illegitimate product; (6) investigating suspect product; (7) notifying FDA of suspect product that is determined not to be illegitimate product (when applicable); (8) processing saleable returns; and (9) establishing systems and processes to comply with all of these requirements.

We assume manufacturers, repackagers, and wholesale distributors will already have systems and processes to comply with many of these requirements. Such systems will therefore only need to be updated to ensure full compliance with the DSCSA. We also anticipate that a chain pharmacy will develop the required systems and processes centrally at its headquarters or at its distribution centers and then distribute to each pharmacy.

Our estimated burden for the information collection reflects some significant increases; most notably burden we attribute to the task of documenting individual transaction information. We have also increased the number of respondents submitting WEE requests.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07569 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

[1] Transaction is defined in section 581(24) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2865]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications

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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 2, 2025.

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 0910–0865. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control Number 0910–0865—Extension

This notice requests extension of OMB approval of the FDA information collection for a generic clearance that allows FDA to use quantitative social/behavioral science data collection techniques (*i.e.,* surveys and experimental studies) to test consumers' reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, it is important to assess communications while they are under development. Understanding consumers' attitudes, motivations, and behaviors in response to potential communications and education messaging plays an important role in improving FDA's communications.

If the following conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally identifiable information (PII) is collected only to the extent necessary [1] and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; [2] and

[1] For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

[2] As defined in OMB and Agency Information Quality Guidelines, ''influential'' means that ''an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.''

• The collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for an individual generic collection submission that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Human Subject Protection Program, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

In the **Federal Register** of July 31, 2024 (89 FR 61453), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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
Cognitive Interviews Screener	720	1	720	0.083 (5 minutes)	60
Cognitive Interviews	144	1	144	1	144
Pre-test Study Screener	2,400	1	2,400	0.083 (5 minutes)	199
Pre-testing Study	480	1	480	0.25 (15 minutes)	120
Self-Administered Surveys/Experimental Studies Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys/Experimental Studies	15,000	1	15,000	0.25 (15 minutes)	3,750
Total					10,498

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07572 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4687]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application

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 June 2, 2025.

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 0910–0337. 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.

Medicated Feed Mill License Application

OMB Control Number 0910–0337—Extension

This information collection helps support implementation of statutory and regulatory provisions related to medicated animal feed mill licensing. Feed manufacturers that seek to manufacture a Type B or Type C medicated feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed using Category I, Type A medicated articles that must follow proprietary formulas or specifications, are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b). Our regulations in 21 CFR part 515 establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using Form FDA 3448 (§ 515.10(b) (21 CFR 515.10(b))). This form may be submitted via U.S. mail or electronically to a dedicated email address, *MedicatedFeedsTeamMail@fda.hhs.gov.* We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a preapproval inspection. Form FDA 3448 may be accessed on our website at: *https://*