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.

Compounding Animal Drugs From Bulk Substances

OMB Control Number 0910–0904—Extension

This information collection helps support recommendations discussed in FDA guidance. Animal drugs compounded from bulk drug substances by pharmacists and veterinarians do not meet certain important requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). To be legally marketed in accordance with animal drug approval requirements of the FD&C Act, an approval, conditional approval, or listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species [1] is required, and compounded drugs do not go through any of these pre-market review processes. (Information collection associated with new animal drug applications is approved under OMB control no. 0910–0032; information collection pertaining to index of legally marketed unapproved new animal drugs for minor species is approved under OMB control no. 0910–0605.) Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (CGMP) requirements and have adequate directions for use, requirements not met by compounded drugs.[2] Thus, drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). However, FDA has generally refrained from taking enforcement action against animal drugs compounded from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist.

To assist respondents in understanding FDA's current thinking about animal drug compounding from bulk substances, our Center for Veterinary Medicine developed GFI #256 entitled ''*Compounding Animal Drugs from Bulk Drug Substances*'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances*). The guidance describes circumstances under which FDA generally does not intend to take enforcement action against pharmacists and veterinarians who compound animal drugs from bulk drug substances.

In the **Federal Register** of May 1, 2025 (90 FR 18665), we published a 60-day notice soliciting comment on the proposed collection of information. Three comments were submitted to the docket by various trade associations, however the first two were not responsive to the information collection topics solicited under 5 CFR 1320.8(d). Rather, the comments appeared to be proffered in accordance with our Good Guidance Practice regulations in 21 CFR 10.115 and we therefore refer the commenters to 21 CFR 10.115(f) regarding how the public may participate in the development of FDA guidance documents. The third comment suggested improvements to increase the utility of Form FDA 1932a, *Veterinary Adverse Drug Reaction, Lack of Effectiveness, Or Product Defect Report,* approved for use in OMB control no. 0910–0291, currently pending OMB review. We appreciate this comment and continue to make technological enhancements to our collection instruments as our limited resources allow. At the same, none of the comments offered an alternative estimate, and we therefore retain the estimate of burden for the information collection as communicated in our 60-day notice, which is as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Documenting rationales by licensed veterinarian/pharmacist compounders in state-licensed pharmacies or Federal facilities.	7,500	1,134	8,505,000	0.017 (1 minute)	144,585

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

We base our estimate on our experience with the regulation of compounded animal drugs. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14226 Filed 7–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5234]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notification Procedures for Statements of Dietary Supplements

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 August 28, 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

[1] Sections 512, 571, and 572 of the FD&C Act (21 U.S.C. 360b, 360ccc, 360ccc–1).

[2] Section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), 21 CFR parts 210 and 211, and section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).

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 0910–0331. 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.

Food Labeling: Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) the name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via the Food Applications Regulatory Management (FARM) system. Firms that prefer to submit a paper notification in an alternative format may opt to do so; however, Form FDA 3955 prompts respondents to include certain data elements in their structure/function claim notification (SFCN), as described in § 101.93, in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (*e.g.,* label), can be submitted in electronic format via FARM. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act. We also provide information on our website at *https://www.fda.gov/food/information-industry-dietary-supplements/notifications-structurefunction-and-related-claims-dietary-supplement-labeling,* which may serve as a helpful resource to respondents.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

In the **Federal Register** of December 19, 2024 (89 FR 103835), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity; Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93; Statements for Dietary Supplements; Form FDA 3955	3,690	1	3,690	0.75 (45 minutes)	2,768

[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. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14222 Filed 7–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0349]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

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 August 28, 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 0910–0752. Also include