

Section 1141.10(g)(4) establishes that each tobacco product manufacturer required to randomly and equally display and distribute warnings on cigarette packages or quarterly rotate warnings in cigarette advertisements in accordance with an FDA-approved plan

under section 4 of the FCLAA and 21 CFR part 1141 must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This

subsection requires that the FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ^{1 2}

21 CFR part 1141 and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Original Submission (Initial Plan) Records	51	1.5	77	3	231
Total	231

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.
² Numbers are rounded.

FDA estimates that 51 recordkeepers will keep a total of about 77 (rounded) records at 3 hours per record for a total of 231 hours. As stated previously, these estimates are based on FDA’s experience with information collections for other tobacco product plans (i.e., smokeless, consolidated under OMB control number 0910–0671). Based on our estimates for the submission of one-time, initial plans and supplements (i.e., that all respondents will submit one-time, initial plans and about half of respondents will submit supplements to FDA-approved plans), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA concludes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB because they do not constitute a “collection of information” under the PRA (44 U.S.C. 3501–3520). Rather, these labeling statements are a “public disclosure” of information originally supplied by the federal government to the recipient for the purpose of “disclosure to the public” (5 CFR 1320.3(c)(2)).

FDA estimates that the total burden for this information collection is 3,381 hours annually (3,150 hours for reporting + 231 hours for recordkeeping). Independently of the public comments received, FDA has adjusted its burden estimate based on updated submission data, which has resulted in a decrease to the currently approved burden. Our estimated reporting burden for the information collection reflects an overall decrease of 76 annual responses and a corresponding decrease of 7,986 annual hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years. These updated estimates are consistent with the scope of this information

collection as described above and do not reflect any changes made in response to public comments.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
 [FR Doc. 2026–10187 Filed 5–20–26; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2026–N–1303]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience/Events With Approved New Animal Drugs

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 June 22, 2026.

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 0910–0284. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, PRASStaff@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.

Adverse Experience/Events With Approved New Animal Drugs

OMB Control Number 0910–0284—Extension

This information collection supports statutory and regulatory requirements governing reporting associated with certain animal drug products. With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4). Regulations in § 514.80 (21 CFR 514.80) require the electronic submission of postmarketing safety

reports for approved new animal drugs but provide a procedure for requesting a temporary waiver from the requirement. We, therefore, retain use of certain paper-based forms. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA.

Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports

under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) on Form FDA 1932 (to include FDA 1932 and 1932a (e-form)). The information collection also includes Form FDA 2301; Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.

The information collection also includes submissions under § 514.80(d)(2), by an applicant or nonapplicant requesting, in writing, a temporary waiver of the electronic submission requirements. The initial request may be by telephone or email to CVM's Division of Pharmacovigilance and Surveillance, with prompt written

follow-up submitted as a letter to the application(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

In the **Federal Register** of February 20, 2026 (91 FR 8245), 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 2}

21 CFR section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated feed reports, 510.301(a) and (b).	N/A	7	1	7	.5 (30 minutes)	3.5
Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3), and (4)(iv)(A) and (C).	1932	85	1262.94	107,350	1	107,350
Voluntary reporting FDA Form 1932a for the public.	1932a	217	1	217	1	217
514.80(b)(4) Periodic Drug Experience Reports.	2301	66	24.68	1,629	16	26,064
514.80(b)(5)(i) Special Drug Experience Reports.	2301	52	363.2	18,886	2	37,772
514.80(b)(5)(ii) Advertisement and Promotional labeling.	2301	35	326.71	11,435	2	22,870
514.80(b)(5)(iii) Distributor's Statements.	2301	13	2.77	36	2	72
514.80(d)(2)	N/A	1	1	1	1	1
Total				139,561		194,349.5

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

² Sums may not total due to rounding.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping, 510.301 ²	7	1	7	4	28
Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e) ³	79	1,575.14	124,436	14	1,742,104
Total			124443		1,742,132

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

² This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.

³ This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and conditional NADAs under § 514.80(e).

Our estimated burden for the information collection reflects an overall increase of 22,073.50 hours and a corresponding increase of 15,117 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years. An increase of safety reports represents a pattern that aligns with expectations—as product availability and usage expand, adverse event reporting increases proportionally. The recent three-year increase appears to be a continuation of this established pattern rather than an indication of new safety concerns.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10189 Filed 5–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0746]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Active Pharmaceutical Ingredients) and the Advanced Manufacturing Technologies Designation Program

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 June 22, 2026.

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 0910–0139. Also include the FDA docket number found in

brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, 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.

Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Active Pharmaceutical Ingredients), and the Advanced Manufacturing Technologies Designation Program

OMB Control Number 0910–0139—Revision

This information collection supports statutory and regulatory requirements that govern the manufacture, processing, packing, or holding of finished pharmaceuticals, including active pharmaceutical ingredients (APIs). Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP regulations. FDA is responsible for enforcing the FD&C Act as well as related statutes, including the Public Health Service Act. Congress enacted these laws to ensure that covered products meet applicable requirements regarding the safety, identity and strength, and the quality and purity characteristics they purport or are represented to possess and are labeled with adequate warnings and instructions for use.

The pharmaceutical or drug quality-related regulations appear in several parts of Title 21 Code of Federal Regulations (CFR) (Food and Drugs), including sections in parts 1 through 99, 200 through 299, 300 through 499, 600 through 799, and 800 through 1299. The regulations enable a common understanding of the regulatory process by describing requirements to be followed by drug manufacturers, applicants, and FDA. The information collection also supports regulations codified under parts 610 and 680 (21 CFR parts 610 and 680), which reference certain CGMP regulations in part 211

(see §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f)). The information collection requirements help FDA ensure compliance with applicable requirements and meet its public health protection responsibilities.

The information collection also includes FDA’s Center for Drug Evaluation and Research’s (CDER) Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) and Circular A–119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing agencies to use voluntary consensus standards developed or adopted by a standards developing organization—rather than Government-unique standards—except where these standards are inconsistent with applicable law or otherwise impractical. The guidance document entitled, “*CDER’s Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality*” (July 2023), outlines justifications for why a standard may be recognized wholly, partly, or not at all. (The guidance document is available for download from our website at: *CDER’s Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality* | FDA.) The guidance document also communicates that interested parties may request recognition of a standard. We intend on finalizing the guidance document upon OMB approval of the attendant information collection.

The information collection also covers activities associated with FDA’s Advanced Manufacturing Technologies (AMT) Designation Program, as provided for in section 506L of the FD&C Act (21 U.S.C. 356l) and added by section 3213 of the Food and Drug Omnibus Reform Act of 2022 (FDORA). The guidance document entitled, *Advanced Manufacturing Technologies Designation Program*, (December 2024), communicates the statutory goals, scope, and framework of the AMT program. The guidance document is available for download from our internet site at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/advanced-manufacturing-technologies-designation-program>.

We are revising the information collection to remove activities and burden attributable to medical gas requirements. Through rulemaking on