

22,564 cosmetic product listing respondents and 25,190 cosmetic product listing renewal respondents. However, these figures may overestimate the total number of unique respondents because some respondents may both list new products in compliance with section 607(c)(1) and (2) of the FD&C Act and renew existing cosmetic product listings under section or update cosmetic product listings 607(c)(5) of the FD&C Act. Additionally, the total number of cosmetic product listing and listing renewal respondents will differ due to variation in the timing of respondents completing initial cosmetic product listings, as well as the voluntary nature of product listing renewals. For cosmetic product listing, we estimate an average of ~ 14.64 responses per respondent, which amounts to 330,337 responses, at an average rate of 1 hour response, for a

total of 330,337 total burden hours. Like facility registration, cosmetic product listing renewals and updates typically involve less information input than the initial product listing which accounts for their smaller average burden per response and total burden hours.

Adverse event reporting is captured on FDA Form 3500A, and the associated data are collected under OMB Control Number 0910–0291 (FDA’s Adverse Event and Product Experience Reporting Program: MedWatch and the Safety Reporting Portal). Under section 605(e)(1) of the FD&C Act, a responsible person must maintain a record for six years (three years for qualifying small businesses) for each adverse event report that they are required to submit. Accordingly, the adverse event recordkeeping estimates presented in Table 1 are aligned with the data collected under OMB Control Number

0910–0291. However, because that information collection combines cosmetics-related adverse event reports with food and infant formula adverse event reports, the actual number of cosmetics adverse event reports may be lower than the figure presented here. We will update the estimate if more precise data becomes available.

We estimate that each of the 22,564 respondents will maintain, on average, one safety substantiation record. Because section 608(a) requires responsible persons to maintain records supporting the “adequate substantiation of safety” of cosmetic products, and because responsible persons have discretion in determining which records satisfy this requirement, we estimate that each respondent will create and maintain at least one record for compliance purposes.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Regulatory authority: information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
21 CFR 701.3: declaration of ingredients in order of pre-dominance	5,738	21	120,498	1	120,498
21 CFR 701.11: statement of identity	5,738	24	137,712	1	137,712
21 CFR 701.12: name and place of business	5,738	24	137,712	1	137,712
21 CFR 701.13: net quantity of contents	5,738	24	137,712	1	137,712
FD&C sec. 609(a): contact information to send adverse event reports	5,738	24	137,712	1	137,712
FD&C sec. 609(c): professional use only	402	12	4,824	1	4,824
Total			676,170		676,170

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

We estimate that 5,738 respondents will expend a total of 120,498–137,712 burden hours annually (21 CFR 701.3, 701.11–13) including required disclosures on an average of 21–24 product labels per respondent. Similarly, we estimate 5,738 respondents will expend a total of 137,712 hours per label annually to ensure that an average of 24 product labels display requisite adverse event reporting information, and that 402 respondents will expend an average of 4,824 hours annually disclosing requisite “professional use only” labeling on an average of 12 products.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7338]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary National Retail Food Regulatory Program Standards

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 November 13, 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 0910–0621. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8758, 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.

Voluntary National Retail Food Regulatory Program Standards

OMB Control Number 0910–0621—Extension

This information collection helps support implementation of FDA’s Voluntary National Retail Food Regulatory Program Standards (the Retail Program Standards). Regulatory Program Standards play a critical role in an integrated food safety system and serve as the foundation for mutual reliance between FDA and other regulatory agencies that work to ensure food safety. The Retail Program Standards define what constitutes a highly effective and responsive program for the regulation of foodservice and retail food establishments. The Retail Program Standards are intended to provide a foundation upon which continuous improvements can be made with the ultimate goal to reduce the occurrence of factors that cause and contribute to foodborne illness. In support of this goal, FDA works cooperatively with our State, local, territorial, and tribal partners using a risk-based approach to leverage limited resources. We engage in education and outreach efforts to facilitate collaboration with our partners in food safety. The Retail Program Standards represent an important component of a comprehensive strategic approach to help ensure the safety and security of the food supply at the retail level.

The Retail Program Standards were revised most recently in November 2024 and include the following elements: (1)

regulatory foundation; (2) trained regulatory staff; (3) inspection program based on Hazard Analysis and Critical Control Point (HACCP) principles; (4) uniform inspection program; (5) foodborne illness and food defense preparedness and response; (6) compliance and enforcement; (7) industry and community relations; (8) program support and resources; and (9) program assessment. These elements are enumerated and discussed on our website at <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024> along with worksheets and assessments that allow FDA to determine conformance with the Retail Program Standards. State, local, territorial, tribal, and Federal regulatory agencies that participate in the voluntary program are required to report information demonstrating that a program self-assessment, a risk factor study of the regulated industry, and an independent outside audit (verification audit) have been completed. The information also includes Form FDA 3958, “Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report,” which may be completed electronically at <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2024>.

We have created a dedicated email at retailfoodprotectionstaff@fda.hhs.gov to receive requests for program documentation and the following instruments to support the

standardization of food safety inspection officer candidates:

- Form FDA 5017, “Standardized Retail Food Safety Inspection Officer Waiver of Annual Maintenance Requirement,” pertains to requests for waivers from maintenance requirements, referenced in section 3–403 of the “FDA Procedures for Standardization of Retail Food Safety Inspection Officers.” FDA uses the information submitted on Form FDA 5017 to determine a retail food safety inspection officer’s eligibility for restandardization.
- Form FDA 5018, “Standardized Retail Food Safety Inspection Officer Annual Maintenance Form,” provides verification that a retail food safety inspection officer has met program standardization requirements in accordance with section 3–403 of the “FDA Procedures for Standardization of Retail Food Safety Inspection Officers.”
- Form FDA 5019, “Standardized Retail Food Safety Inspection Officer Nomination Form,” allows FDA to collect qualification information from retail food safety inspection officer candidates.

Description of Respondents: Respondents to the information collection are State, local, territorial, and tribal regulatory agencies.

In the **Federal Register** of July 17, 2026 (91 FR 44857), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was generally favorable of the collection of information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Voluntary National Retail Program Standards (November 2024)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Program self-assessments for element Nos. 1 through 8.	500	1	500	92.3	46,150
Program element No. 9; risk factor study and intervention strategy.	500	1	500	333	166,500
Program Verification audit	500	1	500	46.15	23,075
Program records; associated documentation/maintenance of worksheets, assessments, associated program tools.	500	1	500	94.29	47,145
FDA Form 3958; VNRFP National Registry Report	500	1	500	0.1 (6 minutes)	50
Requests for program documentation (dedicated email).	500	3	1,500	0.1 (6 minutes)	150
Proposed Form FDA 5017; Waiver of Annual Maintenance Requirement.	10	1	10	0.35 (21 minutes)	4
Proposed Form FDA 5018; Retail Food Safety Inspection Officer Annual Maintenance.	130	1	130	0.35 (21 minutes)	43
Proposed Form FDA 5019; Retail Food Safety Inspection Officer Nomination.	14	1	14	0.35 (21 minutes)	5

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Voluntary National Retail Program Standards (November 2024)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total			4,154		283, 122

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

Our estimate of burden for the associated program activities as identified in table 1 is based on our experience with the information collection, along with other regulatory standards programs we administer. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Cellular, Tissue, and Gene Therapies Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Cellular, Tissue, and Gene Therapies Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cellular, Tissue, and Gene Therapies Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 28, 2028, expiration date.

DATES: Authority for the Cellular, Tissue, and Gene Therapies Advisory Committee will expire on October 28, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring,

MD 20993–0002, (301) 796–8220, ACOMSSubmissions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65, 21 CFR 14.40(b), and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs and biologic products for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of human cells, human tissues, gene therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least six voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene therapies, and xenotransplantation. These may include biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine, and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious

diseases, cellular kinetics, and related specialties.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the Committee and the variety in the types