

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response in hours
Employees/employee representatives/or employers.	HHE Request Form	250	1	12/60
Employees	HHE specific interview example †	1,470	1	15/60
Employees	HHE specific questionnaire example †	2,100	1	30/60
Employees	HHE specific medical survey informed consent form.	60	1	30/60
Employees	Employee Contact Postcard	1,225	1	5/60
Employer & employee representative	Initial Site Visit Followback Survey form	140	1	10/60
Employer & employee representative	Closeout for HHE Followback Survey with site visit.	140	1	20/60
Employer & employee representative	1 Year Later for HHE Followback Survey with site visit.	140	1	15/60
Employer & employee representative	Closeout for HHE without site visit	94	1	10/60
Employer & employee representative	1 Year Later for HHE without site visit	94	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Centers for Medicare & Medicaid Services (CMS), the authorities vested in the Secretary of Health and Human Services under section 1128(b) of the Social Security Act. This delegation revises the limitations from the March 14, 2011, delegation of authority (76 FR 13618), which superseded the September 6, 1984, DOA as to Section F.50.—Limitations of Authority, subsection (1)(c).

CMS requested that the permissive exclusion authority under Section 1128(b) of the SSA be formally delegated to the CMS Administrator. As the agency directly responsible for administering Medicare and Medicaid, CMS is uniquely positioned to investigate, identify, and develop the evidentiary basis underpinning permissive exclusion determinations. Formalizing this delegation aligns investigative and enforcement responsibilities within a single operating division, reducing redundancy and improving program integrity outcomes.

This delegation will be exercised in accordance with the Department's

applicable policies, procedures, guidelines, and regulations. These authorities may be redelegated. Excluded from this delegation is the authority to conduct hearings and to issue regulations. This delegation does not affect or diminish the Secretary's previous delegation of these authorities to the Inspector General of the Department of Health and Human Services under 53 FR 12993 (Apr. 20, 1988), nor does it affect any actions taken pursuant to that earlier delegation.

All redelegations and edits to this authority are required to be reviewed by the Division of Performance and Organizational Programs, Office of Human Capital, CMS, or its successor. Exercise of this authority is in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary. The Secretary retains the authority to submit reports to Congress and promulgate regulations.

This delegation is effective immediately. I affirm and ratify any actions taken by the Administrator or subordinates that involve the exercise of the authorities delegated therein prior to the effective date of the delegation.

Robert F. Kennedy, Jr.,

Secretary.

[FR Doc. 2026–21001 Filed 10–13–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6739]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Cosmetic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 0910–0599. 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, 240–402–5733, 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.

Requirements for Cosmetic Products

OMB Control Number 0910–0599—Revision

This information collection supports the implementation of statutory and regulatory requirements that govern cosmetic products, including requirements most recently established under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA amended the Federal Food, Drug, and Cosmetic Act by adding, in pertinent part, sections 604, 605, 607, 608, and 609 (21 U.S.C. 364b, 364c, 364e, and 364g), which establish or amend definitions and requirements related to adverse events, facility registration, cosmetic product listing, safety substantiation, and labeling. Agency regulations in 21 CFR part 701, subparts A, B, and C (§§ 701.1–701.30), establish cosmetic labeling requirements, including general provisions, package form requirements, and labeling requirements for specific ingredients. Respondents to the information collection consist primarily of responsible persons as defined in

section 604(4) of the FD&C Act, meaning the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.

The respondent totals and burden figures are based on facility registration, cosmetic product listing, and labeling data derived from multiple submission pathways, including Cosmetics Direct, the Electronic Submission Gateway (ESG) Next Generation (NextGen), Structured Product Labeling (SPL) authoring software, and paper submissions. Cosmetics Direct is an online submission tool that allows users to enter required data, generate an SPL submission, and submit facility registrations, product listing, and renewals for cosmetic products directly to FDA. Alternatively, industry may use its own software to create an SPL-formatted submission and transmit the submission to FDA through the ESG.

To assist respondents with information collection and provide an alternative to the ESG NextGen electronic submission process, we have also developed Form FDA 5066, entitled “Registration of Cosmetic Product Facility,” and Form FDA 5067, entitled “Cosmetic Product Listing,” to be used for cosmetic product facility registrations and product listings,

respectively. These forms are available electronically and in paper format at <https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products>.

We have also developed the guidance document, “Registration and Listing of Cosmetic Product Facilities and Products” (December 2024), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-registration-and-listing-cosmetic-product-facilities-and-products>. The guidance document is intended to provide instruction in preparing and submitting registration and product listing information as required by section 607 of the FD&C Act. The guidance document discusses, among other things, who must register and list, when, and what information must be submitted to FDA.

In the **Federal Register** of July 17, 2026 (91 FR 9287), we published a 60-day notice requesting public comment on the proposed collections of information. Although two comments were received, neither discussed the information collection topics found in 5 CFR 1320.8(d)(1) for which the Agency sought comment, nor did they suggest that we revise the figures we attribute to the individual collection tasks.

We estimate the burden of the collections of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Information collection activity; FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sec. 605(e)(1): adverse event recordkeeping	1,165	1.2	1,398	0.6 (36 minutes)	839
Sec. 607(a)(1): initial facility registrations	8,343	1	8,343	0.5 (30 minutes)	4,172
Sec. 607(a)(2) and (5): biennial facility registration renewals and abbreviated facility registration renewals.	2,107	1	2,107	0.17 (10 minutes)	358
Sec. 607(a)(4): facility registration updates	3,141	1	3,141	0.25 (15 minutes)	785
Sec. 607(f): post-hearing corrective action plan	5	1	5	10	50
Sec. 607(c)(1) & (2): initial cosmetic product listing	22,564	14.64	330,337	1	330,337
Sec. 607(c)(3): abbreviated cosmetic product listing renewals	25,190	1	25,190	0.10 (6 minutes)	2,519
Sec. 607(c)(5): cosmetic product listing updates	3,020	8.15	24,613	0.25 (15 minutes)	6,153
Sec. 608(a): safety substantiation recordkeeping	22,564	1	22,564	1	22,564
Total			417,698		367,777

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

Because 5 CFR 1320.3(m) defines a recordkeeping requirement to include the reporting to the Federal government regarding such records, we have denoted table 1 as recordkeeping burden, noting that applicable requirements include the submission of information to FDA. We estimate a total burden of 367,777 hours associated with annual reporting and recordkeeping requirements cumulatively. For facility registration activity, we assume approximately 8,343 annual respondents will engage in initial

facility registration. Respondents are required to register their facility only once and based on internal trials and communication with industry, we estimate that registration will take approximately 30 minutes to complete for a total of 4,172 burden hours. Facility registration renewal occurs every two years. Therefore, the initial facility registration figure does not represent all currently active registrations and may appear low compared to the number of cosmetic

product listing activity respondents. Differences in the timing of respondents completing initial facility registrations account for differences in respondent totals for initial facility registration, registration renewals, and registration updates. Additionally, renewals and updates typically involve less information input than the initial registration which accounts for their smaller average burden per response and total burden hours. For cosmetic product listing activity, we assume a total of approximately

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