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 predominance	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.

[FR Doc. 2026–14434 Filed 7–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6876]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Voluntary Improvement Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection activities associated with the Medical Device; Voluntary Improvement Program.

DATES: Either electronic or written comments on the collection of information must be submitted by September 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–6876 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Voluntary Improvement Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Voluntary Improvement Program—21 CFR Part 820

OMB Control Number 0910–0922—Extension

This information collection supports Food and Drug Administration (FDA, us

or we) implementation of its Voluntary Improvement Program (VIP). Included among the strategic priorities of our Center for Devices and Radiological Health (CDRH) is promoting a culture of quality and organizational excellence. As communicated on our website at *https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/voluntary-medical-device-manufacturing-and-product-quality-pilot-program,* we conducted a pilot project pertaining to voluntary medical device manufacturing and product quality and have incorporated some of the successes and learnings into the VIP. The VIP oversees third-party appraisers who evaluate industry participants. The VIP is facilitated by the Medical Device Innovation Consortium (MDIC), a public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

The guidance document entitled, ''*Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program,*'' communicates our policy regarding participation in the VIP. Only eligible manufacturers of medical devices regulated by CDRH whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (including sections 510(k), 513, 515, and 520) may participate in the VIP. The guidance document was developed and issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance document includes instruction to respondents regarding eligibility, FDA engagement with participants, submission criteria, and withdrawal or removal from the program. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Recommended information collection activity: *Fostering medical device improvement: FDA activities and engagement with the Voluntary Improvement Program*	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Site manufacturer application	1	300	300	0.08	24
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	300	300	20	6,000
Total					6,056

Our estimated burden for the information collection reflects an overall decrease of 2,009 hours and a corresponding decrease of 200 responses. We attribute this adjustment based on our device registration and listing data and informal feedback from stakeholders.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14436 Filed 7–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2026–N–7130]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Accreditation Scheme for Conformity Assessment (ASCA) Program.

DATES: Either electronic or written comments on the collection of information must be submitted by September 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for