

specific statute or charter establishes qualifications, composition, nomination, or selection requirements, those requirements control. This notice does not replace the solicitation of nominations required when FDA establishes a new advisory committee under 21 CFR 14.82(b).

For medical device classification panels, this annual notice also provides the opportunity described in section 513(b)(5)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(5)(D)) for patients, representatives of patients, and sponsors of medical devices that may be specifically subject to review by a classification panel to recommend individuals with appropriate expertise for voting-member positions.

II. Criteria for Voting Members and Appointment Status

In general, nominees should demonstrate subject-matter expertise relevant to one or more FDA advisory committees, the ability to interpret complex scientific or technical information, an understanding of the public health significance of the matters before the committee, and the ability to provide objective and independent advice. FDA will consider the expertise, experience, professional disciplines, and points of view needed for the functions of the particular committee and to support fairly balanced membership.

Voting members serve as individuals and not as representatives of any group or organization that nominated them or with which they are affiliated. Generally, non-Federal voting members are appointed as special Government employees and are subject to applicable Federal ethics and conflict-of-interest requirements. Federal employees may serve as regular Government employees in their official capacities when authorized for the particular committee and position. Certain committees or positions may be governed by different statutory, regulatory, or charter provisions. FDA will determine the appropriate appointment status for each position.

Members generally are invited to serve for overlapping terms of up to 4 years, or for a shorter period at the discretion of the appointing official, subject to the applicable statutes, regulations, and committee charter.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted.

Nominations must include a current, complete résumé or curriculum vitae for each nominee. Nominations must also specify the advisory committee for which the nominee is recommended. Additionally, nominations must acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Only U.S. Citizens, non-citizen U.S. Nationals, and Permanent Residents may apply for service as a committee member.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20063 Filed 9–30–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6876]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Improvement 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 November 2, 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 0910–0922. 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, PRASaff@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.

Medical Devices; Voluntary Improvement Program

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.

In the **Federal Register** of July 17, 2026 (91 FR 44852), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received.

FDA received one comment from an individual. The commenter supported extending the VIP information collection and organized his remarks around the four questions in the 60-day notice, as summarized here:

The commenter affirmed the value of VIP appraisal data as a proactive quality signal and suggested FDA publish de-identified, aggregated benchmark data from appraisal results, particularly to assist smaller manufacturers of high-risk devices during the QMSR transition.

The commenter asserted that the 20-hour estimate for the summary of site appraisal is significantly low for first-time participants and recommended either splitting the estimate into initial and repeat appraisal figures or surveying current VIP participants to validate it. The commenter also noted that if the estimate covers only the incremental reporting burden, the supporting statement should make that scoping assumption explicit. The commenter recommended (1) capturing repeat-nonconformance rates for issues previously closed through CAPA as a complement to maturity scores, and (2) adopting a standardized summary template to improve comparability across sites and appraisal cycles. The commenter suggested (1) offering a structured electronic submission form, (2) pre-populating identifying fields

from existing establishment registration and device listing data, and (3) allowing repeat participants to submit delta reports covering only changes since the last appraisal.

FDA has taken note of the commenter's suggestion to publish de-identified, aggregated benchmark data derived from appraisal results. This information is currently available to VIP participants. As VIP is a voluntary improvement program, not a compliance program, participation data is submitted to FDA by the third-party appraiser with no commitment that it will be shared publicly. Accordingly, FDA does not plan to make this information available to the public at this time.

FDA acknowledges the commenter's concern regarding the accuracy of the 20-hour burden estimate for the summary of site appraisal, particularly as it applies to first-time participants. However, the 20-hour estimate refers to the time spent by the third-party appraiser, not the device manufacturer, to prepare and submit a summary of the site appraisal to FDA. Because this information collection captures the burden imposed on the third-party appraiser, the commenter's experience preparing manufacturing sites for appraisal does not directly relate to this estimate. FDA has not received any information or feedback regarding the accuracy of this estimate of the burden on the third-party appraiser and no changes to this burden estimate are appropriate, based on the comment.

FDA also acknowledges the commenter's suggestion to provide estimates to separate initial vs. subsequent appraisals but has not received any information or feedback relating to accuracy of the 20-hour estimate for the third-party appraiser. (1) FDA has considered the commenter's recommendation to capture nonconformance rates for issues previously closed through CAPA. FDA

acknowledges the comment that recurrence data may provide value not found in maturity scores alone. However, as VIP is a voluntary improvement program and not a compliance program, capturing either recurrence data or reasons for CAPA failure is outside the current scope of the information the program is designed to collect. (2) FDA agrees that comparability across sites and appraisal cycles can be useful under the proper circumstances. However, the VIP is structured so that participants work with the appraisers to create an individualized, mutually-agreed upon appraisal process. As such, each VIP participant firm may focus on a different set of quality measures as part of its appraisal process. As a result of these differences, there would be limited value in comparability across participants and FDA does not plan to make changes to the program to increase comparability.

FDA appreciates the commenter's suggestions for reducing respondent burden. As this is a third-party appraisal program, FDA relies on the third-party appraiser's expertise in implementing a successful appraisal program including determining the method of collecting data and choosing the format of submissions. With respect to pre-populating fields from establishment registration and device listing data, FDA notes that, because these are independent third-party programs, appraisers do not necessarily have direct access to FDA databases and submissions. Furthermore, VIP is not limited to one third party appraiser and may employ different appraisers using different methods. Accordingly, FDA does not believe a common application form or a standardized delta-reporting format based on prior submissions would be appropriate.

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. 2026–20085 Filed 9–30–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Dermatologic and Ophthalmic Drugs 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 Dermatologic and
Ophthalmic Drugs 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 Dermatologic and
Ophthalmic Drugs Advisory Committee
for an additional 2 years beyond the
charter expiration date. The new charter
will be in effect until the October 7,
2028, expiration date.

DATES: Authority for the Dermatologic
and Ophthalmic Drugs Advisory
Committee will expire on October 7,
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
Dermatologic and Ophthalmic Drugs
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 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 and

effectiveness of marketed and
investigational human drug products for
use in the treatment of dermatologic and
ophthalmic disorders and makes
appropriate recommendations to the
Commissioner.

The Committee shall consist of a core
of at least twelve voting members
including two Chairpersons. Subject to
legal and regulatory requirements,
members and the Chairpersons are
selected by and serve at the discretion
of the Commissioner or designee. Each
member, including the Chairpersons,
will be selected from among authorities
knowledgeable in the fields of
dermatology, ophthalmology, dentistry,
immunology, epidemiology or statistics,
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
of issues that it will consider, or other
reason determined appropriate in
accordance with legal and regulatory
requirements. 21 CFR 14.22(d).

If functioning as a medical device
panel, an additional non-voting
representative member of consumer
interests and an additional non-voting
representative member of industry
interests will be included in addition to
the voting members.

Members appointed to an advisory
committee serve for the duration of the
committee, or until their terms expire,
they resign, or they are removed from
membership by the Commissioner or
designee. Committee members' terms
may be ended prior to their date of
expiration, for reasons determined to be
good cause. Good cause includes
excessive absenteeism from committee
meetings, a demonstrated bias that
interferes with the ability to render
objective advice, failure to abide by
established procedures, or violation of
other applicable rules and regulations.

Further information regarding the
most recent charter and other
information can be found at [https://
www.fda.gov/advisory-committees/
dermatologic-and-ophthalmic-drugs-
advisory-committee/dermatologic-and-
ophthalmic-drugs-advisory-committee-
charter](https://www.fda.gov/advisory-committees/dermatologic-and-ophthalmic-drugs-advisory-committee/dermatologic-and-ophthalmic-drugs-advisory-committee-charter) or by contacting the Advisory
Committee Oversight and Management
Staff (see **FOR FURTHER INFORMATION
CONTACT**). Because the committee's
name and description of duties remain
unchanged, 21 CFR 14.100 will not be
amended.

**Renewal Requirements and
Justification:** The Commissioner has
determined that renewal of the
Dermatologic and Ophthalmic Drugs
Advisory Committee is in the public
interest. This determination is based on
the Committee's essential role in
providing independent expert advice on
the safety and effectiveness of marketed
and investigational human drug
products for use in the treatment of
dermatologic and ophthalmic disorders,
the continued need for specialized
expertise in this therapeutic area, and
the Committee's demonstrated value in
supporting FDA's regulatory mission.
The following information supports this
determination in accordance with
applicable legal and regulatory
requirements.