E 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1580]

Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle; Guidance for Industry, Food and Drug Administration Staff, and Other Interested Parties; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle." Patients provide valuable input to FDA in a variety of forms. This guidance describes the principles and concepts that FDA recommends sponsors and other interested parties consider when collecting and submitting patient preference information (PPI), discusses FDA's inclusion of PPI in its decision summaries, and provides recommendations for the inclusion of such information in device labeling for certain devices. PPI can be used in FDA decision making across the total product life cycle, including during review of investigational device exemption (IDE) applications, requests for a Breakthrough Device designation, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, De Novo classification requests, premarket notifications (510(k)s), or for FDA decisions involving administrative, enforcement, or other actions.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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-2015-D-1580 for "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle." Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to

the guidance. Submit written requests for a single hard copy of the guidance document entitled "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA believes that patients can and should bring their own experiences to bear in helping the Agency to evaluate the benefit-risk profiles of certain devices. This kind of input can be important to consider during FDA's decision making for these devices across the total product life cycle. This guidance updates the recommendations in the 2016 guidance entitled "Patient Preference Information--Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling" ("2016 PPI Guidance"). Since the issuance of the 2016 PPI Guidance, there have been many developments in the use of PPI for devices, including an increase in industry-sponsored PPI studies provided to FDA for consideration as part of a benefit-risk assessment, and numerous collaborations between FDA scientists and a variety of interested parties to conduct PPI studies to inform clinical trial design and FDA decision making across a wide range of diseases, conditions, and device areas. FDA has also implemented its benefit-risk framework across the total product life cycle (TPLC), including the submission and review of IDE applications, requests for a Breakthrough Device designation, PMAs, HDE applications, De Novo requests, and 510(k)s, and other FDA decisions involving administrative, enforcement, and other actions. This update of the 2016 PPI Guidance reflects this TPLC scope

as well as developments in the field of health preference research. This final guidance fulfills a commitment in Section V.E. of the Medical Device User Fee Amendments Performance Goals and Procedures, Fiscal Years 2023 Through 2027 (MDUFA V) to update the 2016 PPI Guidance with pragmatic insights and to address common questions for those interested in the use of PPI in regulatory submissions. This guidance supersedes the 2016 PPI Guidance issued on August 24, 2016.

FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M-25-20, and finds this action to be neither regulatory nor deregulatory.

A notice of availability of the draft guidance appeared in the *Federal Register* of September 6, 2024 (89 FR 72856). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying terminology, adding recommendations on when sponsors may find it helpful to meet with FDA, and adding recommendations on when patient engagement during the design and implementation of a study may be beneficial.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at

https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics. Persons unable to download an electronic copy of "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI01500006 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
860, subpart D	De Novo classification process	0910-0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions and Early Payor Feedback Request Programs for Medical Devices	0910-0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910-0485
50, 56	Protection of Human Subjects and Institutional Review Boards	0910-0130

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-06063 Filed: 3/27/2026 8:45 am; Publication Date: 3/30/2026]