



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0514]

Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act." The existing postmarket surveillance guidance was issued in May 2016 to address certain postmarket surveillance requirements. This draft guidance is intended to update the 2016 guidance to increase transparency to stakeholders on FDA's approach to the issuance and tracking of these postmarket surveillance orders, and expectations for timely study completion. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2011-D-0514 for "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act." 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 draft guidance document entitled "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Nilsa Loyo-Berrios, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G114, Silver Spring, MD 20993-0002, 301-796-6065.

SUPPLEMENTARY INFORMATION:

I. Background

Section 522 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360*l*) provides FDA with the authority to require manufacturers to conduct postmarket surveillance at the time of approval or clearance or any time thereafter of certain class II or class III devices. This draft guidance document will assist manufacturers of devices subject to section 522 postmarket surveillance orders by providing:

- an overview of section 522 of the FD&C Act;
- information on how to fulfill section 522 obligations, including:
 - when postmarket surveillance should be considered commenced;
 - recommendations for achieving an approved postmarket surveillance plan in a timely manner; and
 - recommendations for enrollment schedules to help achieve timely completion of postmarket surveillance;
- recommendations on the format, content, and review of postmarket surveillance plan and report submissions, including revised FDA review times for postmarket surveillance-related submissions; and
- updated surveillance status categories to better reflect progress.

This draft guidance document also aims to increase transparency to stakeholders on FDA's approach to the issuance and tracking of 522 postmarket surveillance orders, and expectations for timely study completion.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current

thinking of FDA on "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act." 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 draft 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov> and at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19042 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or Guidance	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 Device Exemption	0910-0332
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910-0844
822	Postmarket Surveillance of Medical Devices	0910-0449

Dated: May 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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