



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-4739]

Requesting FDA Feedback on Combination Products; Guidance for Industry and FDA 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 a final guidance for industry and FDA staff entitled "Requesting FDA Feedback on Combination Products." The purpose of this guidance is to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. These interactions can occur through application-based mechanisms, such as the pre-submission process used in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) and the formal meetings used in the Center for Drug Evaluation and Research (CDER) and CBER, or through Combination Product Agreement Meetings (CPAMs), as appropriate.

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-2019-D-4739 for "Requesting FDA Feedback on Combination Products." 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)).

Submit written requests for single copies of the guidance to the to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5125, 301-796-5616, melissa.burns@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Requesting FDA Feedback on Combination Products." The purpose of this guidance is to discuss ways in which combination product sponsors can obtain feedback from the Agency on scientific and regulatory questions. These interactions can occur through application-based mechanisms, such as the pre-submission process used in CDRH and CBER and the formal meetings used in CDER and CBER, or through CPAMs, as appropriate.

FDA is publishing this guidance consistent with the Agency's ongoing commitment to enhancing clarity and transparency regarding regulatory considerations for combination products, and in accordance with the mandate under section 503(g)(8)(C)(vi) of the Federal Food, Drug, and Cosmetics Act (FD&C Act) (21 U.S.C. 353(g)(8)(C)(vi)), which was added by section 3038 of the 21st Century Cures Act (Pub. L. No. 114-255). Section 503(g)(8)(C)(vi) of the FD&C Act requires FDA to issue a final guidance addressing: (1) the structured process for managing pre-submission interactions with sponsors developing combination products; (2) best practices to ensure FDA feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during these pre-submission interactions; and (3) how CPAMs relate to other FDA meeting types, what information should be submitted prior to a CPAM, and the form and content of agreements reached through a CPAM.

In response to comments received on the draft guidance, this final guidance includes additional information on use of CPAMs and application-based mechanisms. The guidance also provides additional clarity on how CPAMs will be conducted, including expected timelines for CPAM-related activities.

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 "Requesting FDA Feedback on Combination Products." 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. 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 pertaining to orphan drug provisions in 21 CFR part 316 are approved under OMB control number 0910-0167; the collections of information pertaining to investigational device exemption submission provisions in 21 CFR part 812 are approved under OMB control number 0910-0078; the collections of information pertaining to investigational new drug submission provisions in 21 CFR part 312 are approved under OMB control number 0910-0014; the collections of information pertaining to biologics licensing submission provisions in 21 CFR part 601 are approved under OMB control number 0910-0338; and the collections of information pertaining to combination product agreement meetings are approved under OMB control number 0910-0523.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents> or <https://www.regulations.gov>.

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-26700 Filed: 12/3/2020 8:45 am; Publication Date: 12/4/2020]