21 CFR part or guidance	Topic	OMB control No.
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
822	Postmarket Surveillance of Medical Devices	0910–0449
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19402 Filed 9–7–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4848]

Application of Human Factors Engineering Principles for Combination Products: Questions and Answers; 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 ''Application of Human Factors Engineering Principles for Combination Products: Questions and Answers.'' This document provides questions and answers for industry and FDA staff on the application of human factors engineering (HFE) principles to the development of combination products as defined under the regulations. The guidance clarifies how the unique aspects of a combination product influence the considerations within the HFE process. This guidance is intended to facilitate the development of combination products. This guidance finalizes the draft guidance entitled ''Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development'' issued on February 3, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on September 8, 2023.

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–4848 for ''Application of Human Factors Engineering Principles for Combination Products: Questions and Answers.'' 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 this guidance to the Office of

Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002. 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: Patricia Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301–796–8930, *Patricia.Love@fda.hhs.gov* or *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Application of Human Factors Engineering Principles for Combination Products: Questions and Answers.'' This guidance provides questions and answers for industry and FDA staff on the application of HFE principles to the development of combination products as defined under 21 CFR part 3. This guidance should be used in conjunction with the guidance for industry and FDA staff ''Applying Human Factors and Usability Engineering to Medical Devices'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices*) and with the guidance for industry ''Safety Considerations for Product Design to Minimize Medication Errors'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-product-design-minimize-medication-errors-guidance-industry*).

This guidance focuses on considerations for the application of HFE principles to combination products comprised of a medical device combined with a drug or a biological product submitted for review in the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Drug Evaluation and Research. This guidance discusses, among other things, the definition of a combination product critical task, considerations for combination products due to the use of a drug or biological product constituent part together with a device constituent part, training as part of the user interface, and human factors (HF) validation data to support the combination product user interface that may be included in a premarket submission.

This guidance finalizes the draft guidance entitled ''Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development'' issued on February 3, 2016 (81 FR 5764). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: change in format to a questions and answers format, deletion of HF information that is redundant with other FDA guidance documents and focusing the guidance on combination product specific issues, providing additional information in response to comments, clarification of the combination product critical task definition, further explanation of considerations to help identify combination product critical tasks, and replacement of an appendix of examples of user task failures with examples that provide a contextual discussion of combination product critical task considerations. In addition, editorial changes were made to improve clarity.

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 ''Application of Human Factors Engineering Principles for Combination Products: Questions and Answers.'' 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 for 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014 and the collections of information for 21 CFR part 812 for investigational device exemptions have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 314 for new drug applications have been approved under OMB control number 0910–0001 and the collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814, subparts A through E for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 807, subpart E for premarket notifications have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR 860, subpart D for De Novo classifications have been approved under OMB control number 0910–0844.

III. Electronic Access

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

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0984]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pulmonary-Allergy Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 17, 2023, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.