4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1339]

Multiple Function Device Products: Policy and Considerations; 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 a final guidance entitled "Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff." This final guidance provides FDA's regulatory approach for device products with multiple functions including at least one device function and includes such device products that are part of combination products, in accordance with the 21st Century Cures Act (Cures Act).

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-2018-D-1339 for "Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff." 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.

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 "Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff" 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or the Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993-0002, 301-796-5528; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911; or Kristina Lauritsen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6162, Silver Spring, MD 20993-0002, 301-796-8936.

SUPPLEMENTARY INFORMATION:

I. Background

On December 13, 2016, the Cures Act (Pub. L. 114-255) was signed into law. Section 3060(a) of this legislation entitled "Clarifying Medical Software Regulation" amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 520(o) (21 U.S.C. 360j(o)), which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). In addition, section 520(o)(2) of the FD&C Act describes the regulation and assessment of a product with multiple functions including at least one device function and at least one software function that is not a device. Although section 520(o)(2) of the FD&C Act applies to the regulation of software products containing at least one device function and at least one non-device software function, FDA believes that a similar approach should be used for the assessment of all multiple function device products that contain at least one device function and one "other function", which may be a non-device software function; a function that meets the definition of a device, but is not subject to premarket review; or a function that meets the definition of device, but for which FDA has expressed its intention not to enforce compliance with applicable regulatory controls. This approach also applies to multiple function device products that are device constituent parts of combination products. FDA considered comments received on the draft guidance that appeared in the *Federal Register* of April 27, 2018 (83 FR 18570). FDA revised the guidance as appropriate in response to the comments.

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 "Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff." 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.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, or https://www.regulations.gov. Persons unable to download an electronic copy of "Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17038 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information have been approved by OMB as follows:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
803	Medical device reporting	0910-0437
807, subparts A through D	Registration and listing	0910-0625
807, subpart E	Premarket notification	0910-0120
812	Investigational device exemption	0910-0078

814, subparts A through E	Premarket approval applications	0910-0231
814, subpart H	Humanitarian use devices	0910-0332
820	Current good manufacturing practice and the quality system regulation	0910-0073
312	Investigational New Drug Regulations	0910-0014
314	Applications for FDA Approval to Market a New Drug	0910-0001
314	Abbreviated New Drug Applications and 505(b)(2) Applications	0910-0786
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use--Form FDA 356h	0910-0338
"User Fees for 513(g) Requests for Information" and "FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act"	513(g) requests	0910-0705
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo requests	0910-0844

Dated: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-16394 Filed: 7/28/2020 8:45 am; Publication Date: 7/29/2020]