Dated: September 19, 2017.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2017–20460 Filed 9–25–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0429]

Classification of Products as Drugs and Devices and Additional Product Classification Issues; 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 for industry and FDA staff entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' This guidance provides the Agency's current thinking on approaches for classifying products as drugs and devices, and on certain additional product classification issues.

DATES: The announcement of the guidance is published in the **Federal Register** on September 26, 2017.

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–2011–D–0429 for ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' 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 office between 9 a.m. and 4 p.m., Monday through Friday.

- 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.gpo.gov/fdsys/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)).

Submit written requests for single copies of the guidance document entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues'' 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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Associate Director for Policy, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' This guidance finalizes two related draft guidance documents issued in June 2011, entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues'' and ''Interpretation of the Term 'Chemical Action' in the Definition of Device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act.''

This guidance is intended to provide the Agency's current thinking on approaches for classifying products as drugs and devices, and on certain additional product classification issues. FDA determines whether to classify a product as a drug or device based on the statutory definitions for these terms set forth in section 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g) and (h)), respectively, as applied to the scientific data concerning the products

that are available to FDA at the time the classification determination is made.

FDA regularly receives questions from medical product sponsors concerning the classification of their products. We believe that efficient, effective regulation would be facilitated by providing guidance on this topic. This guidance discusses the request for designation (RFD) process for obtaining a formal determination of a product's classification, and provides general concepts regarding FDA's decision process for making classification determinations. While issues have arisen relating to whether a product should be classified as a drug, device, biological product, or combination product, issues most frequently arise regarding whether a product should be classified as either a drug or a device. Accordingly, this guidance focuses particularly on cases in which a product may be classified as a drug or device.

This guidance is organized into two substantive sections. Section II provides information on the RFD process for obtaining a formal determination of whether a product is classified as a drug or device and on obtaining other feedback from FDA on product classification questions. Section III discusses general concepts and definitions relating to FDA's decisional process for making classification determinations and addresses issues that may arise in determining whether products should be classified as drugs or devices.

FDA carefully considered the comments received on the two draft guidances in preparing this final guidance. We have combined the two documents into one and made other changes for clarity and ease of reference. For example, we have revised the discussion of the Agency's interpretation and application of the term ''chemical action'' in the definition of device at section 201(h) of the FD&C Act, to more clearly explain the Agency's approach. With regard to this issue and others, we have also included additional examples to illustrate the application of the Agency's current thinking.

In light of comments received, we have also reconsidered inclusion of content on the status of prior Agency classification determinations. FDA has had limited experience with reevaluating classification determinations as the issue rarely arises for FDA to consider. In addition, it can raise a variety of complex scientific and regulatory questions. Accordingly, we have concluded that it is not appropriate to address the topic further in guidance at this time. We will continue to address the issue on a case-by-case, fact-specific basis as needed, in a transparent manner as permitted by, and consistent with, applicable legal requirements. Any stakeholder who has questions regarding the classification of a currently marketed product or whether that classification should be relied upon with respect to a proposed product is encouraged to contact the Office of Combination Products.

II. Significance of Guidance

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 ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in 21 CFR part 3 have been approved under OMB control number 0910–0523.

IV. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm.*

Dated: September 21, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20522 Filed 9–25–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5319]

Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing on a potential approach for device sponsors who seek to obtain marketing authorization for their products that are labeled for a new use with an approved, marketed drug when the sponsor for the approved drug does not wish to pursue or collaborate on the new use.

DATES: The public hearing will be held on November 16, 2017, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by October 26, 2017. Sections II and III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until January 15, 2018. Late, untimely filed comments will not be considered.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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