



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1159]

Food and Drug Administration Categorization of Investigational Device Exemption Devices to Assist the Centers for Medicare and Medicaid Services with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, 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 guidance entitled "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff." This guidance modifies the FDA's current policy on categorization of investigational device exemption (IDE) devices, which assists the CMS in determining whether or not an IDE device should be covered (reimbursed) by CMS. On December 2, 2015, FDA's Center for Devices and Radiological Health (CDRH) and CMS's Coverage and Analysis Group (CAG) executed a Memorandum of Understanding (MOU) to streamline and facilitate the efficient categorization of investigational medical devices in order to support CMS's ability to make Medicare coverage (reimbursement) determinations for those devices. This guidance document further explains the framework that FDA intends to follow for such categorization decisions.

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 this 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-2016-D-1159 for "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, 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 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 docket, 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.

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 "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff" to the Office of the Center Director, 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. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1682, Silver Spring, MD 20993-0002, 301-796-6356, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for sponsors, clinical investigators, industry, institutional review boards, and FDA staff entitled, "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff." This guidance modifies the FDA's current policy on categorization of IDE devices. In September 1995, FDA entered into an Interagency Agreement (IA) regarding reimbursement categorization of investigational devices with the Health Care Financing Administration (now known as CMS). FDA would assign a device with an approved IDE based on the level of risk the device presented to patients. The categorization would then be used by CMS as part of its determination of whether or not items and services met the requirements for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act. In following with the IA, FDA categorized devices as either Category A ("Experimental") or Category B ("Nonexperimental/Investigational"). In the more than 20 years since the IA was signed, FDA

has received a number of IDEs which do not easily fit into any of the eight sub-categories identified in the IA. There have also been several developments which prompted FDA and CMS to revise their shared understanding regarding the categorization of IDE devices. These include the publication of the guidance document entitled, "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies; Guidance for Industry and Food and Drug Administration Staff," (Ref. 1) and a subsequent increase in submission of early feasibility studies to FDA, as well as modifications to CMS's regulation regarding IDEs (42 CFR 405 Subpart B).

On December 2, 2015, FDA's CDRH and CMS's Coverage and Analysis Group (CAG) executed a Memorandum of Understanding (MOU) to streamline and facilitate the efficient categorization of investigational medical devices. The MOU became effective as of June 2, 2016. This guidance document describes the process and information that will be used to help determine the appropriate category for a device to be studied. Importantly, the categorization paradigm has shifted from a more rigid approach to one which allows more flexibility and could be of great benefit specifically to manufacturers of, and patients receiving, innovative medical devices. The previous categorization paradigm included several specific criteria upon which a categorization would be based. These criteria were tied to information known about other similar, legally marketed products. The policy has been revised in order to allow FDA to consider information known about investigational devices as well, and provide FDA the flexibility to change categorization as more information regarding a device has been obtained. Therefore, while an innovative medical device may not be reimbursable during early-stage clinical trials, information gained during such studies now can be utilized to potentially help

support a category change, and thus full reimbursement, for the device during subsequent studies.

FDA considered comments received on the draft guidance that appeared in the June 1, 2016, *Federal Register* notice (81 FR 35032). FDA revised the guidance as appropriate in response to the comments. This document supersedes IDE Guidance Memorandum #95-2 "Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices" issued on September 15, 1995.

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 "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions." 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. 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 CDRH guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. A search capability for all CBER guidance documents is available at: <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <https://www.regulations.gov>. Persons unable

to download an electronic copy of "FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, 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 1500074 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA and CMS 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 812 have been approved under OMB control number 0910-0078. The collections of information in 42 CFR part 405, subpart B have been approved under OMB control number 0938-1250.

V. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it are also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies; Guidance for Industry and Food and Drug Administration Staff, available at

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279103>.

Dated: November 29, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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