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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6154]

Evaluation of Devices Used With Regenerative Medicine Advanced Therapies; Draft Guidance for Industry; Availability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availability of a draft document entitled “Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Draft Guidance for Industry.” The draft guidance document, when finalized, will provide device manufacturers, applicants, and sponsors engaged in the development of regenerative medicine therapies, with our current thinking regarding evaluation of devices used in the recovery, isolation or delivery of regenerative advanced therapies, which FDA generally refers to as “regenerative medicine advanced therapies” or “RMATs.” Specifically, as required by the 21st Century Cures Act (Cures Act), the draft guidance addresses how FDA intends to simplify and streamline its application of regulatory requirements for combination device and cell or tissue products; what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device; when a device may be limited to a specific intended use with only one particular type of cell; and application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments 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-2017-D-6154 for "Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Draft Guidance for Industry." 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.

- 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 draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 draft document entitled “Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Draft Guidance for Industry.” The draft guidance, when finalized, will provide device manufacturers, applicants, and sponsors engaged in the development of regenerative medicine therapies, with our current thinking regarding evaluation of devices used in the recovery, isolation or delivery of regenerative advanced therapies, which FDA generally refers to as “regenerative medicine advanced therapies” or “RMATs”. Specifically, as required by section 3034 of the 21st Century Cures Act (Pub. L. 114-255) (Cures Act), the draft guidance addresses how FDA intends to simplify and streamline its application of regulatory requirements for combination device and cell or tissue products; what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device; when a device may be limited to a specific intended use with only one particular type of cell; and application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

The issuance of this draft guidance fulfills the statutory requirement set forth in section 3034(a) of the Cures Act. Furthermore, the Agency intends for this document, when finalized, to serve as a source of information about the Agency’s current thinking about a wide range of concepts related to the regulation of devices, as they apply to devices used in the recovery, isolation, and delivery of RMATs. FDA has provided general information in the draft guidance in lieu of specific examples because the Agency does not yet possess a wide body of experience regarding the evaluation of devices used with RMATs , given the recent establishment of the RMAT designation program in the Cures Act.

As we gain more experience with such devices, we intend to incorporate such information into the final guidance. To that end, although you are welcome to comment on any

aspect of the guidance, we encourage commenters to support their comments with information related to specific marketed devices or types of devices that are used in the recovery, isolation, and delivery of RMATs.

Elsewhere in this issue of the *Federal Register*, FDA is announcing the availability of a document entitled “Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry.” Among other things, that document provides information about the RMAT designation program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Evaluation of Devices Used with Regenerative Medicine Advanced Therapies. 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.

II. Paperwork Reduction Act of 1995

This draft 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 807 have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910-0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either
<https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 13, 2017.

Anna K. Abram,

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

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