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**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 the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or to 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993-0002, 240-402-8926; 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 industry entitled

“Providing Regulatory Submissions in Alternate Electronic Format.” This guidance provides recommendations on an alternate electronic format for submissions that are covered under an exemption from or granted a waiver of the requirements of section 745A(a) of the FD&C Act (21 U.S.C. 379k-1). These recommendations pertain to the electronic format of content in NDAs, ANDAs, certain DMFs, certain BLAs, and certain INDs submitted to the Center for Drug Evaluation and Research or to the Center for Biologics Evaluation and Research.

This guidance includes information on: (1) How to submit in alternate electronic format (without XML backbone), (2) submission of FDA forms, (3) pre-submission considerations, (4) submission structure, (5) file formats and versions, (6) datasets and study information, (7) transmitting electronic submissions, and (8) receipt dates.

This guidance finalizes the draft guidance of the same title issued on March 11, 2020 (85 FR 14202). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to final guidance include: (1) Minor edits to clarify recommendations for the location of the Table of Contents for the alternate electronic format, (2) an example of the folder structure, and (3) the process for submission if an electronic signature is not possible. 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). This final guidance represents FDA’s current thinking on “Providing Regulatory Submissions in Alternate Electronic Format.” 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 in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 314 have been approved under OMB control

number 0910-0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

### **III. Electronic Access**

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: June 28, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2021-N-0008]

### **Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on August 3, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002,

aden.asefa@fda.hhs.gov, 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On August 3, 2021, the committee will discuss and make recommendations on information regarding the premarket notification (510(k)) submission for the TriGUARD 3 Cerebral Embolic Protection Device. The proposed indication for use for the TriGUARD 3 Cerebral Embolic Protection Device, is as follows:

The TriGUARD 3 Cerebral Embolic Protection Device is designed to minimize the risk of cerebral damage by deflecting embolic debris away from the cerebral circulation during transcatheter aortic valve replacement.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 27, 2021. Oral presentations from the public will be scheduled between approximately 1 p.m. Eastern Time and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should

notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 21, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 20, 2021.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov) or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 28, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-D-2323]

**Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications; 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

guidance for industry entitled "Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications." Transdermal delivery systems are designed to deliver a drug across the skin and into systemic circulation, whereas topical delivery systems are designed to deliver the drug to local tissue. There is pharmaceutical and other stakeholder interest in the development of new transdermal and topical products, and this guidance provides recommendations on the clinical assessment of adhesion for such products that will be submitted as new drug applications (NDAs) or supplemental new drug applications. This guidance provides additional study design and methodology recommendations on conducting in vivo adhesion studies. This guidance takes these developments into consideration. When final, this draft guidance will expand upon the recommendation for in vivo adhesion studies in section V., Special Topics, subsection A., Product Adhesion Considerations, in the draft guidance for industry Transdermal and Topical Delivery Systems—Product Development and Quality Considerations issued on November 21, 2019.

**DATES:** Submit either electronic or written comments on the draft guidance by August 31, 2021 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 on any 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