SUPPLEMENTARY INFORMATION:

AGENCY: 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, 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, 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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.” Topical 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 guideline 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 guideline 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 this 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, Room 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–2020–D–2233 for “Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications.” 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. Fail to post 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, Room 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 draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Koher, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5376, Silver Spring, MD 20993–0002, 301–796–0934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications.” 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. 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.

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