I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Eosinophilic Esophagitis: Developing Drugs for Treatment.'' This guidance provides FDA's current recommendations regarding clinical trials for drugs and therapeutic biologics for the treatment of eosinophilic esophagitis, including attributes of patients for enrollment, trial designs, efficacy considerations, safety assessments, and pediatric considerations.

This guidance finalizes the draft guidance of the same name issued February 6, 2019 (84 FR 2237). Changes to the guidance took into consideration public comments received. Major changes included:

- Removal of the recommendation for the proton pump inhibitor trial before patient enrollment;
- removal of the recommendation for exclusion of patients with significant strictures;
- addition of a clarification that FDA does not recommend a randomized withdrawal design for trials of drugs with the potential to induce immunogenicity;
- addition of a recommendation to report eosinophil density per square millimeter (mm^2) as well as per high-power field;
- creation of a statistical section with recommendations on estimands; and
- addition of a clarification on the recommendation for the number of adolescent patients to be included in adult trials.

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 ''Eosinophilic Esophagitis: Developing Drugs for Treatment.'' 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

This final guidance contains no collection 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.

However, this final guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 (investigational new drug applications) have been approved under OMB control number 0910–0014. The collections of information in part 314 (new drug applications) have been approved under OMB control number 0910–0001. The collections of information in part 601 (biologics license applications) have been approved under OMB control number 0910–0338. The collections of information in parts 50 and 56 (protection of human subjects and institutional review boards) have been approved under OMB control number 0910–0130. The collections of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/media/86377/download*) have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: September 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20436 Filed 9–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

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

AGENCY: Food and Drug Administration, Health and Human Services (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 October 27, 2020, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings 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 Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, 301–796–0400, *aden.asefa@fda.hhs.gov,* 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* 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 October 27, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Neovasc Reducer System sponsored by Neovasc, Inc. The proposed Indication for Use of the Neovasc Reducer System is for patients suffering from refractory angina pectoris despite guideline directed medical therapy, who are unsuitable for revascularization by coronary artery bypass grafting or by percutaneous coronary intervention.

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, and the background materials will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/circulatory-system-devices-panel.*

Select the link for the 2020 Meeting Materials. 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 October 9, 2020. Oral presentations from the public will be scheduled on October 27, 2020, 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 October 1, 2020. 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 October 2, 2020.

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: September 11, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20446 Filed 9–15–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Extension of Comment Period for Proposed Updates to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HRSA is providing notice of a technical issue in the collection of public comments responding to a previous **Federal Register** notice, dated August 20, 2020, submitted to the American Academy of Pediatrics through its publicly available web-based portal during the period from August 20–27, 2020. After receiving no comments during this timeframe, a routine test found that the database that records public comments was not connected to the comment form on the web page. This technical issue has been resolved and the system is functional and collecting comments. HRSA encourages members of the public who may have previous submitted comments to resubmit and is extending the time period for public comments in response to proposed updates to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care (''Bright Futures Periodicity Schedule''). The Bright Futures Periodicity Schedule is part of the HRSA-supported preventive service guidelines for infants, children, and adolescents under, and is maintained, in part, through a national cooperative agreement, the Bright Futures Pediatric Implementation Program.

DATES: The comment period published in the **Federal Register** on August 20, 2020, at 85 FR 51454–01 is extended. Members of the public are invited to provide written comments no later than October 16, 2020. All comments received on or before this date will be reviewed and considered by the Bright Futures Periodicity Schedule Workgroup and provided for further consideration by HRSA in determining the recommended updates that it will support.

ADDRESSES: Members of the public interested in providing comments can do so by accessing the public comment web page at: *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html.*

FOR FURTHER INFORMATION CONTACT: Bethany Miller, HRSA, Maternal and Child Health Bureau, email: *BMiller@hrsa.gov,* telephone: (301) 945–5156.

SUPPLEMENTARY INFORMATION: On August 20, 2020, HRSA published a notice soliciting public comments regarding proposed updates to the Bright Futures Periodicity Schedule (85 FR 51454–01). Due to technical issues, comments that may have been submitted between August 20, 2020, and August 27, 2020, were not captured. To ensure that all comments are received and considered, the public is encouraged to resubmit any comments that were provided in response to the notice published on August 20, 2020 (85 FR 51454–01) and also is extending the time period for public comments.

HRSA has funded the Bright Futures Program as a cooperative agreement since 1990. A primary focus of this program is for the funding recipient to maintain and update the Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents, a set of materials and tools for providing quality preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program's existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child's development.

Under section 2713 of the Public Health Service Act, 42 U.S.C. 300gg–13, non-grandfathered group health plans and health insurance issuers must include coverage, without cost sharing, for certain preventive services, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued. These include preventive health services provided for in the Bright Futures Periodicity Schedule as part of the HRSA-supported Preventive Services Guidelines for Infants, Children, and Adolescents. A panel of pediatric primary care experts convened to review the latest evidence and recommends updating the Bright Futures Periodicity Schedule to include screening all individuals ages 18 and older at least once for hepatitis C virus infection. This proposed update aligns with the United States Preventive Services Task Force's recommendation that all adults ages 18 to 79 be screened