

encephalitis vaccine. No recommendation votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on September 1, 2021. Written comments must be received on or before September 30, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the September 29–30, 2021, ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 11:59 p.m., EDT, September 24, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled

time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email September 28, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0651]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. Matters considered at the meeting will include discussion of the toxicity risks of adeno-associated virus (AAV) vector-based gene therapy products. The discussion topics include oncogenicity risks due to vector genome integration and safety issues identified during preclinical and/or clinical evaluation. The meeting will be open to the public on both days. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 2 and 3, 2021, from 10 a.m. 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 about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>. The online web conference meeting will be available at the following links on the day of the meeting: Day 1 https://youtu.be/58KjL9_p9Tw and Day 2 <https://youtu.be/yLggQF0XUUY>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0651. The docket will close on September 1, 2021. Submit either electronic or written comments on this public meeting on or before September 1, 2021. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 1, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before August 26, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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-2021-N-0651 for “Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.” FDA 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 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 the 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>.

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.

FOR FURTHER INFORMATION CONTACT:

Jarrold Collier or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, ctgtac@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, before coming to the meeting, 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.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The CTGTAC committee will meet in open session on both days to discuss the toxicity risks of AAV vector-based gene therapy products. The discussion topics include oncogenicity risks due to vector genome integration and safety issues identified during preclinical and/or clinical evaluation. On September 2, 2021, in the morning, under session 1, the CTGTAC committee will meet to discuss and make recommendations on vector integration and oncogenicity risks. In the afternoon under session 2, the committee will discuss and make recommendations on hepatotoxicity issues. On September 3, 2021, in the morning under session 3, the committee will meet to discuss and make recommendations on thrombotic microangiopathy issues. In the

afternoon under session 4, the committee will discuss and make recommendations on non-clinical findings of neurotoxicity, especially related to the dorsal root ganglion toxicity issues. Also, in the afternoon under session 5, the committee will discuss and make recommendations on clinical findings of neurotoxicity, based on brain magnetic resonance imaging studies.

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. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before August 26, 2021, will be provided to the committee. Oral presentations from the public will be scheduled twice each day between approximately 12:45 p.m. and 1:15 p.m. and 4:05 p.m. and 4:35 p.m. on September 2, and between 11 a.m. and 11:30 a.m. and 1:50 p.m. and 2:20 p.m. on September 3. Individuals interested in making formal oral presentations should notify the contact person and submit 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 August 18, 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 August 19, 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 Jarrod Collier at ctgtac@fda.hhs.gov (see **FOR FURTHER INFORMATION CONTACT**) 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/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> 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: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-15783 Filed 7-23-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-Z-0025]

Medical Devices; Class I Surgeon's and Patient Examination Gloves

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Final order, determination.

SUMMARY: The Department of Health and Human Services (HHS or “the Department”) issued a Notice in the **Federal Register** of January 15, 2021, (“the January 15 notice”) which identified seven types of reserved class I devices that the Department had determined no longer require premarket notification. The Department and the Food and Drug Administration (FDA or “the Agency”) issued a Notice in the **Federal Register** of April 16, 2021 (“the April 16 notice”) explaining the basis for our current view that the seven types of reserved class I devices identified in the January 15 notice require a premarket notification, and explaining why the reasoning supporting the prior determination was unsound. HHS and FDA sought comment on the matters discussed in the April 16 notice, and have considered the comments that were submitted to the docket. HHS and FDA are issuing this final order and determination that the seven types of class I surgeon's gloves and patient

examination gloves listed in the January 15 notice are reserved class I devices for which a premarket notification is required.

DATES: *Compliance date:* All devices subject to this order shall comply with the order no later than August 25, 2021.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT:

Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1660, Silver Spring, MD 20993, 301-796-6380, or by email at RPG@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background Regarding Section 510(l) of the FD&C Act

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. The Medical Device Amendments of 1976 (“1976 amendments”) (Pub. L. 94-295), and the Safe Medical Devices Act of 1990 (Pub. L. 101-629), require FDA to classify devices into class I (“general controls”) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (“special controls”), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Unless a device is exempt from premarket notification, section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, part 807 of Title 21 of the Code of Federal Regulations (CFR), require persons who

intend to market a new device to submit a premarket notification (510(k)) demonstrating the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device for which premarket approval is not required. Section 510(l)(1) of the FD&C Act, added to the statute by the Food and Drug Administration Modernization Act of 1997 (FDAMA), provides that a 510(k) is not required for a class I device, except for any class I device intended for a use that is of substantial importance in preventing impairment of human health, or any class I device that presents a potential unreasonable risk of illness or injury. FDA refers to these as the “reserved criteria” and to class I devices subject to 510(k) as “class I reserved devices.” Thus, class I devices are exempt from the 510(k) requirements except for class I device types that meet the reserved criteria under section 510(l)(1).

As discussed in the April 16 notice, since 2017, FDA has evaluated which devices meet the reserved criteria several times. See 86 FR 20167 at 20168. Each time, FDA has made its determinations available to the public through publication in the **Federal Register**. See 63 FR 5387, 63 FR 63222, 65 FR 2296, 82 FR 17841, 84 FR 71794. In 1998, after FDAMA was enacted, FDA evaluated all class I devices in interstate commerce at that time, and published a notice in the **Federal Register** containing: (1) A list of device types that FDA believed met the reserved criteria and thus would remain subject to premarket notification and (2) a list of device types that FDA believed did not meet these criteria and thus would be exempt from such requirements. See 63 FR 5387. Although devices that did not meet the reserved criteria became exempt on February 19, 1998, FDA also issued proposed and final rules amending the applicable classification regulations for these devices, as well as for five device types that FDA had exempted prior to FDAMA that, post-FDAMA, FDA determined meet the reserved criteria. See 63 FR 63222, 65 FR 2296.

On December 13, 2016, the 21st Century Cures Act (Cures Act) amended section 510(l) of the FD&C Act, reorganizing section 510(l) into paragraphs 510(l)(1) and (2). Section 510(l)(2) of the FD&C Act requires FDA to identify at least once every 5 years, through publication in the **Federal Register**, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness.