inadequate generic competition. For instance, some drugs may not attract a high level of interest from generic drug applicants if there is a limited market for the products and/or if the products are more difficult to develop. Nevertheless, these drugs can play an important role in diagnosing, treating, and preventing various types of diseases or conditions, and incentivizing generic competition for these products can help ensure that patients have access to the medicines they need. The provisions associated with CGTs are intended to incentivize effective development, efficient review, and timely market entry for drugs for which there is inadequate generic competition.

This guidance provides a description of the process that applicants should follow to request designation of a drug as a CGT and the criteria for designating a drug as a CGT. Also, this guidance includes information on the actions that FDA may take to expedite the development and review of ANDAs for drugs designated as a CGT. These actions may help to clarify applicants' regulatory expectations for a particular drug, assist applicants in developing a more complete submission, and ultimately both promote a more efficient and effective ANDA review process and help reduce the number of review cycles necessary to obtain ANDA approval. In addition, this guidance provides information on how FDA implements the 180-day exclusivity period under FDARA for certain first approved applicants that submit ANDAs for drugs designated as CGTs. FDARA created a new type of 180-day exclusivity, different from 180-day patent challenge exclusivity, for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of original submission of the ANDA. This new 180-exclusivity under FDARA (''CGT exclusivity'') is intended to incentivize competition for drugs that are not protected by a patent or exclusivity and for which there is inadequate generic competition.

This guidance finalizes the draft guidance entitled ''Competitive Generic Therapies'' issued on February 19, 2019 (84 FR 4826). FDA considered comments received on the draft guidance as the guidance was finalized. Editorial changes were made to clarify that each applicant should request CGT designation for a drug product that is subject of their application. We have also clarified that, although FDA may expedite development and strive to act on applications for drug products with a CGT designation prior to the Generic Drug User Fee Amendments (GDUFA) goal date, a CGT designation does not result in a shorter GDUFA goal date. Additional explanation was also added to note that pre-ANDA meetings may be granted for both complex and non-complex products on a case-by-case basis and that these meetings are intended to expedite development, but that they will not necessarily take place on an expedited basis. We also updated terminology to further delineate 180-day patent exclusivity from 180-day CGT exclusivity. Finally, editorial changes were made to clarify the operation of 180-day CGT exclusivity and forfeiture.

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 ''Competitive Generic 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 314.94, including the submission of ANDAs and requests for CGT designation, have been approved under OMB control number 0910–0001 (including 0910–0338 for Form FDA 356h). The collections of information associated with product development meetings, presubmission meetings, and mid-review cycle meetings between applicants and FDA have been approved under OMB control number 0910–0797.

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: March 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05293 Filed 3–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2456]

Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies; 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 final guidance for industry entitled ''Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies.'' This document provides guidance to sponsors on the evidence necessary to demonstrate the effectiveness of investigational new drugs or new drug uses intended for slowly progressive, low-prevalence rare diseases that are associated with substrate deposition and are caused by single enzyme defects.

This guidance applies only to those low-prevalence rare diseases with a well-characterized pathophysiology and in which changes in substrate deposition can be readily measured in relevant tissue or tissues. This guidance incorporates the comments received for and finalizes the draft guidance of the same name issued on July 27, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on March 16, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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–2018–D–2456 for ''Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies.'' 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.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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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 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: Hylton Joffe, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6300, Silver Spring, MD 20993–0002, 301–796–1954; 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 final guidance for industry entitled ''Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies.'' This document provides guidance to sponsors on the evidence necessary to demonstrate the effectiveness of investigational new drugs or new drug uses intended for slowly progressive, low-prevalence rare diseases that are associated with substrate deposition and are caused by single enzyme defects. This guidance applies only to those low-prevalence rare diseases with a well-characterized pathophysiology and in which changes in substrate deposition can be readily measured in relevant tissue or tissues.

This guidance finalizes the draft guidance of the same name issued on July 27, 2018 (83 FR 35653). FDA considered comments received on the draft guidance in devising this final guidance. Changes from the draft to the final guidance include the following: clarification that a ''low prevalence'' condition may be defined as one affecting a very small population (*e.g.,* approximately a few thousand persons or fewer in the United States); clarification that, in the absence of nonhuman data to guide a potentially efficacious dose, animal toxicology data can inform a safe starting human dose; and removal of language regarding assay versus intrasubject variability—approaches to manage intrasubject variability within specific drug development programs can be addressed via formal sponsor meetings with the relevant division at FDA.

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 ''Slowly Progressive, Low-Prevalence Rare Diseases With Substrate Deposition That Results From Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). 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 50 have been approved under OMB control number 0910–0755. The collections of information for expedited programs 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 *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: March 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05335 Filed 3–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Cellular, Tissue, and Gene Therapies 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 Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on May 8, 2020, from 1 p.m. to 4:55 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/ctgtac050820/.*

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, *christina.vert@fda.hhs.gov,* or 240–402–8106, *joanne.lipkind@fda.hhs.gov,* respectively, 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 coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On May 8, 2020, the committee will meet by teleconference. In open session, the committee will hear an overview and updates of research programs in the Tumor Vaccines and Biotechnology Branch (TVBB) and Cellular and Tissue Therapy Branch (CTTB), Division of Cellular and Gene Therapies (DCGT), Office of Tissues and Advanced Therapies (OTAT), CBER, FDA.

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 at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On May 8, 2020, from 1 p.m. to 3:40 p.m., the meeting is open to the public. 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 May 1, 2020. Oral presentations from the public will be scheduled between approximately 2:40 p.m. to 3:40 p.m. Those 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 April 23, 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 April 24, 2020.

Closed Committee Deliberations: On May 8, 2020, from 3:55 p.m. to 4:55 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 Christina Vert (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/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: March 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05333 Filed 3–13–20; 8:45 am]

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