DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3499]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Alternative Form of Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of alternative form of hearing.

SUMMARY: The Food and Drug Administration (FDA) announces an alternative form of hearing regarding the Center for Drug Evaluation and Research's (CDER's) proposal to refuse to approve ITCA 650 (exenatide in DUROS device), a drug-device combination product that is the subject of a new drug application (NDA) submitted by Intarcia Therapeutics, Inc. (Intarcia). CDER is holding a public hearing before an advisory committee under FDA regulations as an alternative form of hearing.

DATES: The meeting will be held virtually on September 21, 2023, from 9 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing 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: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, email: *EMDAC@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area).

SUPPLEMENTARY INFORMATION:

Background: This advisory committee meeting is being held pursuant to a March 24, 2023, letter from the Chief Scientist of FDA, Dr. Namandjé N. Bumpus, wherein she granted Intarcia's request under § 12.32(b)(3)(ii) (21 CFR 12.32(b)(3)(ii)) for a public hearing before an advisory committee in lieu of a formal evidentiary public hearing under part 12 (21 CFR part 12).

Intarcia submitted NDA 209053 for ITCA 650 (exenatide in DUROS device), a novel drug-device combination product on November 21, 2016, under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(1)). On September 21, 2017, CDER issued a complete response (CR) letter to Intarcia under § 314.110(a) (21 CFR 314.110(a)) stating that NDA 209053 could not be approved in its present form, describing the specific deficiencies and, where possible, recommending ways that Intarcia might remedy these deficiencies. On September 9, 2019, Intarcia resubmitted the NDA under section 505(b)(1) of the FD&C Act. On March 9, 2020, CDER issued a second CR letter stating that NDA 209053 could not be approved in its present form, describing the specific deficiencies and, where possible, recommending ways that Intarcia might remedy these deficiencies. The CR letters stated that Intarcia is required either to resubmit the application, fully addressing all deficiencies listed in the letter, or take other actions available under § 314.110 (*i.e.,* resubmit the application, withdraw the application, or request an opportunity for a hearing). Applicable regulations, including 21 CFR 10.75, also provide a mechanism for applicants to obtain formal review of one or more decisions reflected in a CR letter.

On March 16, 2021, Intarcia submitted a request under § 314.110(b)(3) for an opportunity for a hearing on whether there are grounds under section 505(d) of the FD&C Act for denying approval of NDA 209053. In the **Federal Register** of September 2, 2021, FDA published a notice of opportunity for a hearing (NOOH) regarding CDER's proposal to refuse to approve NDA 209053 submitted by Intarcia for ITCA 650 (86 FR 49334). The NOOH gave Intarcia an opportunity to request a hearing before the Commissioner of Food and Drugs on CDER's proposal to refuse to approve NDA 209053. On September 13, 2021, Intarcia submitted a notice of participation and request for a hearing. Intarcia submitted data, information, and analyses in support of its hearing request on November 1, 2021, and February 15, 2022.

On July 29, 2022, CDER issued, via email to Intarcia, a proposed order proposing to refuse to approve NDA 209053 in its present form (see Docket No. FDA–2021–N–0874). Intarcia responded to CDER's proposed order on October 10, 2022.

On February 7, 2023, the Chief Scientist of FDA issued a letter to Intarcia and CDER that stated, in part: ''Under 21 CFR 12.32(a), a person seeking a hearing under 21 CFR part 12 may request an alternative form of hearing, such as a hearing before a public advisory committee under 21 CFR part 14.'' Dr. Bumpus stated that she would grant a request from Intarcia for an alternative form of hearing under part 14 (21 CFR part 14) in lieu of a formal evidentiary hearing under part 12. On February 20, 2023, Intarcia submitted a request in the form of a citizen petition under 21 CFR 10.30, requesting a public hearing before an advisory committee under part 14 in lieu of Intarcia's pending request for a formal evidentiary hearing under part 12. On March 24, 2023, Dr. Bumpus issued a letter granting Intarcia's request for an alternative form of hearing.

Accordingly, CDER is holding this meeting pursuant to the March 24, 2023, letter from Dr. Bumpus, wherein she granted Intarcia's request under § 12.32(b)(3)(ii) for a public hearing before an advisory committee in lieu of a formal evidentiary hearing. This document serves as the notice of an alternative form of hearing as required under § 12.32(e).

Subject of Alternative Form of Hearing: CDER's proposed order to refuse to approve ITCA 650 (exenatide in DUROS device) is the subject of the alternative form of hearing before the Endocrinologic and Metabolic Drugs Advisory Committee (see Docket No. FDA–2021–N–0874).

Parties to the Alternative Form of Hearing: Intarcia Therapeutics, Inc. and the Center for Drug Evaluation and Research are the parties to the alternative form of hearing before the Endocrinologic and Metabolic Drugs Advisory Committee.

Issues To Be Discussed: The issues presented at the hearing will be those related to the safety and efficacy of ITCA 650, a drug-device combination product that is the subject of an NDA submitted by Intarcia (NDA 209053), for the proposed indication, as an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by

this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: August 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18241 Filed 8–23–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2436]

Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice announcing the availability of a draft guidance entitled ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry,'' that appeared in the **Federal Register** of July 14, 2023. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance published July 14, 2023 (88 FR 45222). Submit either electronic or written comments on the draft guidance by November 13, 2023, to ensure that we consider your comment on the draft guidance before we begin 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 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–2023–D–2436 for ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry.'' 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.'' We will review this copy, including the claimed confidential information, in our 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Karen Fikes, 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: In the **Federal Register** of July 14, 2023 (88 FR 45222), we published a notice of availability for a draft guidance entitled ''Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry.'' This action opened a docket with a 60-day comment period.

We have received requests for a 30-day extension of the comment period for the draft guidance. We have considered the requests and are extending the comment period for the draft guidance for 60 days, until November 13, 2023. (A 60-day extension would fall on November 11, 2023, which is a Saturday, so we have extended the comment period until the next business day, which is November 13, 2023.) We believe that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: August 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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