unresectable or metastatic esophageal squamous cell carcinoma:

- sBLA 125514/S–096 for KEYTRUDA (pembrolizumab) injection, submitted by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.;
- sBLAs 125554/S–105 and S–106 for OPDIVO (nivolumab) injection, submitted by Bristol Myers-Squibb Co.; and
- sBLA 125377/S–122 for YERVOY (ipilimumab) injection, submitted by Bristol Myers-Squibb Co.

The Committee will also discuss the new BLA 761380 for tislelizumab, submitted by BeiGene USA, Inc., for the same proposed indication.

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 and/or video conference meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/Advisory Committees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The online presentation of materials will include slide presentations with audio and video components 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 to the Docket (see **ADDRESSES**) on or before September 12, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 11:45 a.m. and 4:45 p.m. to 5:15 p.m. Eastern Time. 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, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before September 4, 2024. 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. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by September 5, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

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 Joyce Frimpong (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. 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 in conjunction with the physical meeting room (see location). 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. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18970 Filed 8–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3788]

Electronic Submission Template for Medical Device De Novo Requests; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Electronic Submission Template for Medical Device De Novo Requests.'' FDA is issuing this guidance to introduce submitters of De Novo requests to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) to the current resources and associated content developed and made publicly available to support De Novo electronic submissions to FDA. This guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.

DATES: The announcement of the guidance is published in the **Federal Register** on August 23, 2024.

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–2023–D–3788 for ''Electronic Submission Template for Medical Device De Novo Requests.'' 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. 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.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Electronic Submission Template for Medical Device De Novo Requests'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Lisa Lim, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1108, Silver Spring, MD 20993–0002, 301–796–6443; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance document to introduce submitters of De Novo requests [1] to CDRH and CBER to the current resources and associated content developed and made publicly available to support De Novo electronic submissions to FDA. This guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.[2] This guidance facilitates the implementation of FDA's mandate under section 745A(b) of the FD&C Act, amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52 [3]) to provide further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

FDA's guidance document ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' [4] (hereafter referred to as the ''745A(b) device parent guidance'') provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format. As described in the 745A(b) device parent guidance, FDA plans to implement the requirements of section 745A(b)(3) of the FD&C Act with individual guidances specifying the formats for specific submissions and corresponding timetables for implementation. This guidance will provide such information for De Novo electronic submissions solely in electronic format.

A notice of availability of the draft guidance appeared in the **Federal Register** of September 29, 2023 (88 FR 67309). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification of the use of technical screening during acceptance review and inclusion of the date when the use of eSTAR for De Novo Requests will become mandatory.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this guidance provides such

[1] See section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) Act and 21 CFR part 860, subpart D.

[2] See 163 CONG. REC. S4729–S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/102699/download,* and 168 CONG. REC. S5194–S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/158308/downloadand* 168 CONG. REC. S5194–S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/158308/download.*

[3] *https://www.govinfo.gov/content/pkg/PLAW-115publ52/html/PLAW-115publ52.htm.*

[4] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.*

requirements under section 745A(b)(3) of the FD&C Act (*i.e.,* standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See § 10.115(d).)

To the extent that this guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on Electronic Submission Template for Medical Device De Novo Requests. 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. This guidance contains both binding and nonbinding provisions.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Electronic Submission Template for Medical Device De Novo Requests'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00021027 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
860, subpart D	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18983 Filed 8–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0874]

Final Decision on the Proposal To Refuse To Approve a New Drug Application for ITCA 650

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) refusing to approve a new drug application (NDA) submitted by Intarcia Therapeutics, Inc., an i2o Therapeutics Business Unit, (Intarcia) for ITCA 650 (exenatide in DUROS device). FDA has determined that the approval criteria in the FD&C Act have not been met because Intarcia has failed to demonstrate that ITCA 650 is safe for its intended conditions of use.

DATES: This notice is applicable August 23, 2024.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Factual and Procedural Background

ITCA 650 (exenatide in DUROS device) is a novel drug-device combination product for human patients intended to deliver the active ingredient, exenatide, a glucagon-like peptide-1 receptor agonist (GLP–1 RA). Intarcia proposed that ITCA 650 be indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. ITCA 650 is intended to provide continuous dosing of exenatide from an osmotic mini-pump implanted in the subdermal space of the abdomen for 3 months for initiation of therapy and every 6 months afterwards for maintenance therapy. ITCA 650 must be inserted and removed by a healthcare provider trained on the included placement tool and guide. ITCA 650 is proposed in two dosage strengths: 20 micrograms (mcg)/day for 3 months and 60 mcg/day for 6 months. The drug formulation used in ITCA 650 is a viscous, non-aqueous suspension. Each mini-pump of ITCA 650—20 mcg/day for 3 months and 60 mcg/day for 6 months—nominally contains 2.56 milligrams (mg) and 14.05 mg of synthetic exenatide, respectively.

On November 21, 2016, Intarcia submitted NDA 209053 for ITCA 650. In support of its NDA, Intarcia included three phase 3 clinical trials to establish substantial evidence of safety and effectiveness—CLP–103, CLP–105, and CLP–107. CLP–107, also known as FREEDOM, was a cardiovascular outcome trial (CVOT). On September 21, 2017, the Center for Drug Evaluation and Research (CDER) issued a complete response (CR) letter to Intarcia stating that the NDA could not be approved in its present form. On September 19, 2019, Intarcia resubmitted the NDA, and on March 9, 2020, CDER issued a second CR letter stating that the NDA could not be approved in its present form, describing specific deficiencies and, where deemed possible, recommending ways that Intarcia might remedy those deficiencies.

On March 16, 2021, after pursuing formal dispute resolution, Intarcia submitted a request under 21 CFR 314.110(b)(3) for an opportunity for a hearing on whether there are grounds under section 505(d) of the FD&C Act (21 U.S.C. 355(d)) for refusing to approve the NDA for ITCA 650. CDER subsequently published a notice of opportunity for a hearing (NOOH) regarding a proposal to refuse to approve the NDA (86 FR 49334