TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Phentermine hydrochloride; Topiramate.
Posaconazole.
Pramipexole dihydrochloride.
Progesterone.
Promethazine hydrochloride.
Quetiapine fumarate.
Tacrolimus.
Tapentadol hydrochloride.
Tiotropium bromide.
Tramadol hydrochloride.
Trospium chloride.
Venlafaxine hydrochloride.
Verteporfin.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–18997 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–2024–N–3647]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Immune Checkpoint Inhibitors in Patients With Unresectable or Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma and Esophageal Squamous Cell Carcinoma

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 26, 2024, from 8 a.m. to 6:15 p.m. Eastern Time.

ADDRESSES: The public may attend the meeting at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, 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.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–3647. The docket will close on September 25, 2024. 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 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 12, 2024, 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–2024–N–3647 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Immune Checkpoint Inhibitors in Patients with Unresectable or Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma and Esophageal Squamous Cell Carcinoma.'' 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: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7973, email: *ODAC@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 FDA'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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: During the morning session, the Committee will discuss the use of immune checkpoint inhibitors in patients with unresectable or metastatic gastric and gastroesophageal junction adenocarcinoma. The current labeling for approved checkpoint inhibitors in this indication reflects broad approvals in the intent to treat patient populations agnostic of programmed death cell ligand-1 (PD-L1) expression. Cumulative data have shown that PD-L1 expression appears to be a predictive biomarker of treatment efficacy in this patient population; however, clinical trials have used different approaches to assess PD-L1 expression and different thresholds to define PD-L1 positivity. FDA would like the Committee's opinion on the following:

• adequacy of PD-L1 expression as a predictive biomarker for patient selection in this patient population;

• differing risk-benefit assessments in different subpopulations defined by PD-L1 expression; and

• adequacy of the cumulative data to restrict the approvals of immune checkpoint inhibitors based on PD-L1 expression.

The Committee will discuss the existing supplemental biologics license applications (sBLA) which were approved for patients with previously untreated HER2-negative unresectable or metastatic gastric or gastroesophageal adenocarcinoma:

• sBLA 125554/S–091 for OPDIVO (nivolumab) injection, submitted by Bristol Myers-Squibb Co.; and

• sBLA 125514/S–143 for KEYTRUDA (pembrolizumab) injection, submitted by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.

The Committee will also discuss BLA 761417 for tislelizumab injection, submitted by BeiGene USA, Inc., for the same proposed indication.

During the afternoon session, the Committee will discuss the use of immune checkpoint inhibitors in patients with metastatic or unresectable esophageal squamous cell carcinoma. The current labeling for approved checkpoint inhibitors in this indication reflects broad approvals in the intent to treat patient populations agnostic of PD-L1 expression. Cumulative data has shown that PD-L1 expression appears to be a predictive biomarker of treatment efficacy in this patient population; however, clinical trials have used different approaches to assess PD-L1 expression and different thresholds to define PD-L1 positivity. FDA would like the Committee's opinion on the following:

• adequacy of PD-L1 expression as a predictive biomarker for patient selection in this patient population;

• differing risk-benefit assessments in different subpopulations defined by PD-L1 expression; and

• adequacy of the cumulative data to restrict the approvals of immune checkpoint inhibitors based on PD-L1 expression.

The Committee will discuss the existing sBLAs which were approved for patients with previously untreated

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/AdvisoryCommittees/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