suggestion and will implement the revision.

We also received comment that some users have experienced ''timing out'' while completing Form FDA 3500B online and requested that any time limit for completing online forms be extended. We were not aware of this issue and will investigate to see whether it relates to the online functionality of the form. If so, we will make the necessary adjustments.

While we are especially appreciative of the comments received in response to our notice, we continue to welcome feedback at all times regarding ways we might improve the MedWatch Program and the associated forms. In addition to the revisions discussed previously, on our own initiative we are now including burden associated with written submissions under § 329.100(c)(2) (21 CFR 329.100(c)(2)) that request a temporary waiver from the electronic reporting requirements associated with postmarket adverse drug events under section 760 of the FD&C Act. While we expect few such waiver requests, we retain a placeholder for one respondent annually, and we estimate it takes 1 hour to complete the request.

We therefore estimate the burden for the information collection as follows.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center or 21 CFR section and/or FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form 3500	14,727	1	14,727	0.66 (40 minutes)	9,720
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80, and 1271.350).	599	98	58,702	1.21	71,029
Form 3500A (§ 310.305 outsourcing facilities)	50	2	100	1.21	121
Center for Devices and Radiological Health:					
Form 3500	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (part 803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition:					
Form 3500	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products:					
Form 3500	39	1	39	0.66 (40 minutes)	26
All Centers:					
Form 3500B	13,750	1	13, 750	0.46 (28 minutes)	6,325
Written requests for temporary waiver under § 329.100(c)(2):	1	1	1	1	1
Total					909,396

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

While we retain the currently approved estimate for the information collection, as noted previously we have added burden associated with written submissions under § 329.100.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19742 Filed 9–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3010]

Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient.'' This public workshop is intended to discuss potential candidate biomarkers to determine organ transplant patients' immunologic risk for organ rejection or tolerance. The public workshop will include discussion of the biomarker qualification process and how it could be used to develop biomarkers for use in clinical trials in transplantation, to develop new drugs to address unmet needs, and in clinical practice to guide patient treatment selection. Speakers will be patients who will provide perspective on the challenges of living with a transplant, managing immunosuppression and perspectives on tolerability, adherence, and risk that may inform patient-reported outcome (PRO) and patient-focused drug development.

DATES: The public workshop will be held on September 27, 2018, from 8:30 a.m. to 6 p.m. and September 28, 2018, from 8 a.m. to 12:30 p.m. Submit either electronic or written comments on this public workshop by November 19, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 19, 2018. The

https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 19, 2018. 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.

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–N–3010 for ''Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Derek Alberding or Ramou Pratt, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0963, *derek.alberding@fda.hhs.gov*, or 301–796–3928, *ramou.pratt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop entitled ''Evidence-Based Treatment Decision in Transplantation: Patient Individualized Treatment; Choosing the Right Regimen for the Right Patient.'' This public workshop is intended for academic experts, industry, healthcare providers, patients, other U.S. Government Agencies, and other stakeholders.

II. Topics for Discussion at the Public Workshop

Presentations and discussions will cover identifying potential candidate biomarkers that could:

- Be considered for the biomarker qualification process
- be used in identifying patients at high immunologic risk or low immunologic risk
- be used in clinical trials to develop drugs to address unmet individual needs in transplantation
- be used to make appropriate immunosuppressive regimen treatment decisions

In addition, patient speakers will provide perspectives on:

- Challenges of living with a transplant,
- managing immunosuppression, and
- tolerability, adherence, and risk of therapy.

The goal of these presentations is to inform PRO and patient-focused drug development.

III. Participating in the Public Workshop

Registration: Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by September 14, 2018, midnight Eastern Time. To register, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to *TransplantationWorkshop2018@fda.hhs.gov.*

Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Derek Alberding or Ramou Pratt (see **FOR FURTHER INFORMATION CONTACT**) no later than September 13, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and

organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 14, 2018. All requests to make oral presentations must be received by September 10, 2018. If selected for presentation, any presentation materials must be emailed to *TransplantationWorkshop2018@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) no later than September 19, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at *https://collaboration.fda.gov/ebtd092018/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm605761.htm.*

Dated: September 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19816 Filed 9–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3308]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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 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 October 10, 2018, from 8 a.m. to 1 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.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–3308. The docket will close on October 9, 2018. Submit either electronic or written comments on this public meeting by October 9, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 9, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 9, 2018. 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 October 1, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

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–2018–N–3308 for ''Oncologic Drugs 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.

- 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.