

reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. We utilized the upper-bound estimate of 1,200 for these calculations.

We estimate that notifying the immediate previous source(s) will take 0.6 hours per reportable food and notifying the immediate subsequent recipient(s) will take 0.6 hours per reportable food. We also estimate that it will take 0.6 hours for the immediate previous source and/or the immediate subsequent recipient to also notify their

immediate previous source(s) and/or immediate subsequent recipient(s). The Agency bases its estimate on its experience with mandatory and voluntary reports submitted to FDA.

Although it is not mandatory under FDAAA, section 1005 that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification

burden will not affect voluntary reporters of reportable food events. Therefore, we estimate that the total burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under section 417(d)(6)(B)(i) and (ii), (d)(7)(C)(i) and (ii) of the FD&C Act for 1,200 reportable foods will be 2,880 hours annually (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours). This annual burden is shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity/Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—mandatory reports.	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—voluntary reports.	4	1	4	0.25 (15 minutes)	1
Total	301

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

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications under section 417 of the FD&C Act for a period of 2 years. Based on past FDA experiences, we estimate that each mandatory report and its associated notifications will require 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours (1,200 × 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore, we estimate that records will be kept for four voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 1 hour annually (4 × 0.25 hours). The estimated total annual recordkeeping burden will be 301 hours annually (1,200 × 0.25 hours) + (4 × 0.25 hours). This annual burden is shown in table 2.

Dated: June 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2734]

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 or Agency) 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 the Agency on FDA’s regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The public meeting will be held on July 12, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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/>

Advisory Committees/ About Advisory Committees/ ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2017-N-2734. The docket will close on July 10, 2017. Submit either electronic or written comments on this public meeting by July 10, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 10, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight eastern time, July 10, 2017. 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 June 26, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2017-N-2734 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 Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, 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 the Agency's Web site 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: The committee will discuss biologics license application (BLA) 125646, for tisagenlecleucel-T suspension for intravenous use. The application was submitted by Novartis Pharmaceuticals Corp. The proposed indication (use) for this product is for the treatment of pediatric and young adult patients 3 to 25 years of age with

relapsed/refractory B-cell acute lymphoblastic leukemia (ALL).

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 Web site 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 Web site 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: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before June 26, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 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 June 16, 2017. 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 June 19, 2017.

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 special accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.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: June 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-11818 Filed 6-6-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2094]

Developing Rabies Monoclonal Antibody Products as a Component of Rabies Post-Exposure Prophylaxis; 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 a public workshop regarding development of rabies monoclonal antibody products to be used in conjunction with licensed rabies vaccine as part of a rabies post-exposure prophylaxis (PEP) regimen. This public workshop is intended to provide information for, and gain perspective from, health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders on various aspects of development efforts pertaining to animal models, laboratory assays, and clinical trials.

DATES: The public workshop will be held on July 17, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop on or before July 31, 2017. See the **SUPPLEMENTARY INFORMATION**

section for registration date and information. The workshop draft Agenda will be made available at: <http://www.fda.gov/Drugs/NewsEvents/ucm540832.htm> prior to the meeting.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), 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 July 31, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of July 31, 2017. 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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2017-N-2094 for "Developing Rabies Monoclonal Antibody Products as a Component of Rabies Post-Exposure Prophylaxis." 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 Division of Dockets Management 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 Division of Dockets Management. 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 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.