



4164-01-P

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.

SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing a public workshop regarding development of rabies monoclonal antibody products to be used in conjunction with a licensed rabies vaccine as part of rabies PEP.

Rabies immunoglobulin, in combination with rabies vaccine, is currently recommended for rabies PEP following suspected or proven rabies exposure. Rabies monoclonal antibody products may offer a potential alternative to rabies immunoglobulin as a component of rabies PEP.

## II. Topics for Discussion at the Public Workshop

FDA is conducting this workshop to discuss the scientific work needed to advance the development of rabies monoclonal antibodies targeting rabies viruses for use in a PEP regimen. Discussions are planned around the following topics:

- Rabies epidemiology and vectors
- Current rabies PEP standard of care
- Scientific challenges of assessing the likely effects of rabies monoclonal antibodies
- Potential utility of animal models and laboratory assays in rabies monoclonal antibody development
- Clinical trial design challenges related to the scientific evaluation of rabies monoclonal antibody efficacy as a component of rabies PEP
- Ethical considerations regarding potential clinical trial designs

The Agency encourages health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

## 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 July 12, 2017, midnight Eastern Time. To register, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to

RabiesWorkshop2017@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 Jessica Barnes or Lori Benner (see FOR FURTHER INFORMATION CONTACT) no later than July 12, 2017.

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. 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 July 11, 2017. All requests to make oral presentations must be received by July 10, 2017, midnight Eastern Time. If selected for presentation, any presentation materials must be emailed to RabiesWorkshop2017@fda.hhs.gov no later than July 13, 2017. 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 the following Web site: <https://collaboration.fda.gov/r6811zievzz/>.

If you have never attended a Connect Pro event before, please test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](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](https://www.adobe.com/go/connectpro_overview).

FDA has verified the Web site addresses in this document, as of the date this document publishes in the Federal Register, but Web sites 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 Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm540832.htm> approximately 45 days after the workshop.

Dated: May 31, 2017.

Anna K. Abram,

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

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