DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–0178]

Guidance for Industry on Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.'' The purpose of this guidance is to provide sponsors and manufacturers FDA's current thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and implementing regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marjorie Shapiro, Center for Drug Evaluation and Research (HFD–123), Food and Drug Administration, 9000 Rockville Pike, Bethesda, MD 20892, 301–827–0710, or Henry Startzman, Office of Orphan Products Development, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.''

On July 26, 1999 (64 FR 40381), FDA announced the availability of the draft version of this guidance. The public comment period closed on October 25, 1999. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

In the **Federal Register** of December 29, 1992 (57 FR 62076), FDA published the orphan drug regulations final rule, and on June 12, 2013 (78 FR 35117) the Agency finalized certain amendments to the final rule in order to clarify regulatory provisions and make minor improvements to address issues that have arisen since 1992. The final rule established in part 316 (21 CFR part 316) regulations that prescribe certain incentives for the development of ''orphan drugs'', drugs which are intended for use in rare diseases or conditions. One of the incentives for orphan drug development is to obtain exclusive approval for the pioneer product for a period of 7 years during which no approval will be given to a subsequent sponsor of the same drug product for the same indication unless it proves to be clinically superior, as defined in § 316.3(b)(3). In determining whether or not two products would be considered the same, FDA recognized that different criteria were necessary for macromolecules versus small molecules (§ 316.3(b)(13)).

Macromolecules include a variety of structures including proteins, nucleic acids, carbohydrates and closely related, complex, partly definable drugs such as live viral vaccines. The current definition of sameness for protein drugs (§ 316.3(b)(13)(ii)(A)), however, does not consider the unique nature of antibodies. This final document is intended to describe FDA's thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and its implementing regulations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These 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. 3501–3520) and have been approved under OMB control numbers 0910–0167 (21 CFR part 316), 0910–0001 (21 CFR part 314), and 0910–0014 (21 CFR part 312).

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09220 Filed 4–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0247]

Food and Drug Administration Transparency Initiative: Increasing Public Access to the Food and Drug Administration's Compliance and Enforcement Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: As part of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Food and Drug Administration Transparency Initiative: Increasing Public Access to FDA's Compliance and Enforcement

Data.'' This report summarizes findings and recommendations from eight FDA working groups established to enhance the transparency and public accessibility of the Agency's compliance and enforcement data.

FOR FURTHER INFORMATION CONTACT: Daniel W. Sigelman, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD 20993, 301–796–4706, FAX: 301–847–8616, email: *daniel.sigelman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a report entitled ''FDA Transparency Initiative: Increasing Public Access to FDA's Compliance and Enforcement Data.'' FDA is responsible for a broad range of compliance and enforcement activities. Increasing the transparency of these activities enhances the public's understanding of the Agency's decisions and promotes accountability of the Agency and the regulated industry.

On October 3, 2011, FDA issued a report entitled, ''Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data.'' The report advanced eight draft proposals for making FDA's publicly available compliance and enforcement data more accessible and user-friendly (available at: *http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf*). Following extensive public comment on the report and internal FDA deliberation, the FDA Commissioner adopted all eight draft proposals, committing FDA to exploring numerous avenues for increasing the transparency and public accessibility of its compliance and enforcement data (see 77 FR 5027, February 1, 2012, and *http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm289638.htm*).

To develop plans for addressing the eight initiatives, FDA established eight working groups with representatives from all of FDA's centers and several of its offices. Each group was asked to draft a report on its initiative and to include recommendations for moving forward. These efforts culminated in the preparation of this report, which summarizes the eight initiatives and the recommendations from the relevant working groups for enhancing the transparency and public accessibility of FDA's compliance and enforcement data.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09188 Filed 4–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Biomedical Imaging and Bioengineering.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Biomedical Imaging and Bioengineering, including consideration of personal qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Biomedical Imaging and Bioengineering.

Date: June 1, 2014.

Time: 7:30 p.m. to 9:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Date: June 2, 2014.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892.

Date: June 3, 2014.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard D. Leapman, Intramural Scientific Director, National Institute of Biomedical Imaging, and Bioengineering, Bethesda, MD 20892, 301–496–2599, *leapmanr@mail.nih.gov*.

Dated: April 17, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–09224 Filed 4–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Special Topic: R21 Re-review.

Date: April 24, 2014.

Time: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: David B Winter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301–435–1152, *dwinter@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS and AIDS Related Research.

Date: April 28, 2014.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.