

symptoms in adult patients with active ankylosing spondylitis; (5) reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy (ABP 501 would be indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab); (6) inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP) (the effectiveness of ABP-501 would not be established in patients who have lost response to or were intolerant to TNF blockers); and (7) treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate (only to be administered to patients who will be closely monitored and have regular follow-up visits with a physician).

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 <http://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. Written submissions may be made to the contact person on or before June 27, 2016. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 3 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 17, 2016. 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 20, 2016.

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 accommodations due to a disability, please contact Moon Hee Choi 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 <http://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. app. 2).

Dated: June 9, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-14017 Filed 6-13-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1273]

Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment; Draft Guidance for Industry; 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 draft guidance for industry entitled "Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment." This draft guidance provides recommendations to industry for designing a nonclinical development program to support approval of drugs to treat osteoporosis. This guidance also discusses the nonclinical development of biopharmaceuticals (e.g., recombinant proteins and monoclonal antibodies).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2016-D-1273 for "Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions,” publicly viewable at <http://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 <http://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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gemma Kuijpers, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5374, Silver Spring, MD 20993–0002, 301–796–1243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment.” This draft guidance provides recommendations to industry for designing a nonclinical development program to support approval of drugs to treat osteoporosis. In addition to the pharmacology and toxicology studies required to support development of a new drug or biologic, long-term nonclinical studies to evaluate effects on bone quality in adequate animal models and including bone-specific pharmacologic and toxicologic endpoints are needed.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on nonclinical evaluation of drugs intended for the treatment of osteoporosis. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

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

Dated: June 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13988 Filed 6–13–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health IT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings are open to the public.

Name of Committee: Health IT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the Health IT Policy Committee.

2016 Meeting Dates and Times

- May 17, 2016, from 9:00 a.m. to 3:00 p.m./Eastern Time
 - This will be an in-person meeting at the Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC 20008
- June 8, 2016, from 9:30 a.m. to 12:00 p.m./Eastern Time
 - This will be a virtual meeting
- June 23, 2016, from 9:00 a.m. to 3:00 p.m./Eastern Time
 - This will be an in-person meeting at the Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202
- July 27, 2016 from 10:00 a.m. to 1:00 p.m./Eastern Time (replacing the formerly announced July 13 and August 7 meetings)
 - This will be a virtual meeting

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, <http://www.healthit.gov/FACAS/calendar>.

Contact Person: Michelle Consolazio, email: michelle.consolazio@hhs.gov. Please email Michelle Consolazio for the most current information about meetings. 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.

Agenda: The committee will hear reports from its workgroups/task forces