

projects (Arkansas, Arizona, Colorado, Hawaii, Illinois, Kentucky, Maine, Maryland, Massachusetts, Michigan, Nebraska, Nevada, New York, Oklahoma, Oregon, Pennsylvania, Port Gamble S'Klallam Tribe, Rhode Island, Tennessee, Texas, Utah, Washington, Washington DC, West Virginia, Wisconsin). The Web-based survey will be administered once during the

National Study. The respondents to the Well-Being telephone survey will be a purposive sample of 60 respondents identified from up to 12 waiver jurisdictions who are involved with the assessment of child and family well-being in their waiver jurisdictions. The Well-Being telephone survey will be administered once during the National Study. The respondents to the Practice

and Systems-Level Change telephone survey will be a purposive sample of 60 respondents identified from up to 12 waiver jurisdictions who are knowledgeable about practice, policy, and organizational changes in their respective waiver jurisdictions. The Practice and Systems-Level Change telephone survey will be administered once during the National Study.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Web-Based Survey	250	1	0.33	82.5
Telephone Survey: Well-Being	60	1	1	60
Telephone Survey: Practice and Systems-Level Change	60	1	1	60
Estimated Total Annual Burden Hours				202.5

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collected described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C St. SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information (c) the quality, utility and clarity of the information to be collected, and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Arthritis 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.

DATES: The meeting will be held on July 12, 2016, from 7:30 a.m. to 5 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: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Moon Hee V. Choi, 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, AAC@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 <http://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 761024, for ABP 501, a proposed biosimilar to AbbVie Inc.'s HUMIRA (adalimumab), submitted by Amgen, Inc. The proposed indications (uses) for this product are: (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs)); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older (alone or in combination with methotrexate); (3) reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (alone or in combination with non-biologic DMARDs); (4) reducing signs and

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.

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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