4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3172]

Osteoporosis Drug Development; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration's (FDA or Agency) Division of Bone, Reproductive, and Urologic Products in the Center for Drug Evaluation and Research is announcing a public workshop entitled "Osteoporosis Drug Development: Moving Forward." The purpose of this workshop is to seek input from experts on scientific issues important to clinical development of drugs and therapeutic biologics intended to treat osteoporosis. During the workshop, attendees will discuss potential surrogate endpoints and the endpoints' ability to predict clinical benefit.

Date and Time: The workshop will be held on November 4, 2015, from 8 a.m. to 5 p.m. Registration to attend the workshop must be received by October 21, 2015. See the SUPPLEMENTARY INFORMATION section for information on how to register for this workshop. Submit electronic or written comments by October 7, 2015.

Location: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, in Sections B and C of the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed.

For more information on parking and security procedures, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Samantha Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5379, Silver Spring, MD 20993-0002, 301-796-9687, email: Samantha.Bell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop entitled "Osteoporosis Drug Development: Moving Forward." The Agency will engage experts in osteoporosis to address challenging issues related to osteoporosis drug development. Workshop sessions will include discussions on the indication language, target populations for treatment and prevention of osteoporosis, and phase 3 clinical trial design issues. The afternoon discussion session will focus on surrogate endpoints for fracture and the requirements for validation of a surrogate endpoint. This workshop is part of the Agency's program to facilitate the development of surrogate endpoints, clinical endpoints, and other scientific methods for predicting clinical benefit, in accordance with section 901 of the Food and Drug Administration Safety and Innovation Act, signed into law on July 9, 2012, which is titled "Enhancement of Accelerated Patient Access to New Medical Treatments."

II. Participation in the Public Workshop

A. Registration and Requests for Oral Presentations

There is no fee to attend the public workshop, but attendees should register in advance. Space is limited and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at Osteoporosis_Workshop@fda.hhs.gov on or

before October 21, 2015. When registering, please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. For those without Internet access, please contact Samantha Bell (see Contact Person) to register. If you need special accommodations due to a disability, please contact Samantha Bell (see Contact Person) at least 7 days in advance.

The afternoon session will have an open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues related to osteoporosis drug development. Those individuals interested in making formal oral presentations should notify the contact person and submit the following information on or before October 21, 2015: 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. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. 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 requests to speak by October 28, 2015.

B. Comments

Regardless of whether you attend this meeting, you can submit either electronic comments regarding this public workshop to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document and must be received by December 29,

2015. 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.

C. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (see Comments) and at http://www.regulations.gov approximately 30 days after the workshop. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at http://www.fda.gov.

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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