In the **Federal Register** of October 23, 2013 (78 FR 63219), FDA published a notice announcing the availability of a draft guidance entitled ''Q3D Elemental Impurities.'' The notice gave interested persons an opportunity to submit comments by December 23, 2013.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on December 16, 2014.

The guidance establishes permitted daily exposures for 24 elements in drug products and provides for a risk-based approach to assessing the likelihood that elemental impurities with established permitted daily exposures will be present in a pharmaceutical product. In response to comments on the draft guidance, several changes were made to the final guidance including clarifying the scope, reevaluation of some permitted daily exposures based on new toxicology data, simplification of the classification scheme for elemental impurities, and clarifying the examples to illustrate certain concepts within the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Q3D elemental impurities. It does 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. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Electronic Access

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

Dated: September 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22835 Filed 9–9–15; 8:45 am]

BILLING CODE 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.

[FR Doc. 2015–22784 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3056]

Distributor Labeling for New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GIF) #231 entitled ''Distributor Labeling for New Animal Drugs.'' This draft guidance discusses FDA's current thinking with respect to the factors it considers in determining whether to take regulatory action against distributor labeling for a new animal drug that differs from the labeling approved as part of a New Animal Drug Application or Abbreviated New Animal Drug Application (NADA/ANADA) in ways other than those permitted by regulation.

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 November 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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.

Submit electronic comments on the draft 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: Dorothy McAdams, Center for Veterinary Medicine, Division of Surveillance (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5763, email: *dorothy.mcadams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #231 entitled ''Distributor Labeling for New Animal Drugs.'' ''Distributor labeling'' refers to the labeling of an approved new animal drug marketed by a distributor who distributes the product under its own label or proprietary name. Unlike the approved labeling, which the Center for Veterinary Medicine reviews as part of a NADA/ANADA approval process to ensure the safe and effective use of the drug and compliance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and its implementing regulations, distributor labeling does not ordinarily go through a premarket approval process.

FDA regulations (21 CFR 514.80) require that distributor labeling be identical to the labeling approved in the NADA/ANADA, except for a different and suitable proprietary name and the name and address of the distributor preceded by an appropriate qualifying phrase. These requirements are meant to ensure that distributor labeling complies with the requirements of the FD&C Act and its implementing regulations and to prevent distributor label products from reaching the market with labeling that compromises the safe and effective use of the new animal drug.

II. Significance of Guidance

This level 1 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 distributor labeling for new animal drugs. 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.

III. Paperwork Reduction Act of 1995

This draft 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). The collections of information in § 514.80 have been approved under OMB control number 0910–0284.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of