an exception to the prohibition against expansion of facility capacity. As required by the November 30, 2011final rule and our public guidance documents, HBC submitted the data and certifications necessary to demonstrate that it satisfies the criteria to qualify as a high Medicaid facility. In accordance with section 1877(i)(3) of the Act, we have granted HBC's request for an exception to the expansion of facility capacity prohibition based on the following criteria:

- HBC is not the sole hospital in Vigo, Indiana, the county in which it is located;
- HBC certified that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; and
- With respect to each of the 3 most recent fiscal years for which data were available as of the date HBC submitted its request, it has an annual percentage of total inpatient admissions under Medicaid that is estimated to be greater than such percentage with respect to such admissions for any other hospital located in Vigo County, Indiana, the county in which it is located.

Our approval grants HBC's request to add a total of 44 beds. Pursuant to § 411.362(c)(6), the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which HBC is licensed to exceed 200 percent of its baseline number of operating rooms, procedure rooms, and beds. HBC certified that its baseline number of operating rooms, procedure rooms, and beds is 44. Accordingly, we find that granting an additional 44 beds will not exceed the limitation on a permitted expansion.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 18, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–22856 Filed 9–9–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1156]

International Conference on Harmonisation; Guidance on Q3D Elemental Impurities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q3D Elemental Impurities.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance establishes permitted daily exposures for 24 elements in drug products based on evaluation of toxicity data. Permitted daily exposures are provided for each element by three routes of administration—oral, parenteral and inhalation. The guidance also 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. The guidance is intended to provide a harmonized approach to control of elemental impurities in pharmaceutical products in order to avoid the uncertainty and duplication of work that results from different requirements in different ICH regions.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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: *Regarding the guidance:* John Kauffman, Center for Drug Evaluation and Research, Food and Drug Administration, 645 S. Newstead Ave., St. Louis, MO 63110, 314–539–2168;

Regarding the ICH: Michelle Limoli, CBER International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7212, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

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