4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Regional Public Workshop on the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Q3D Implementation of Guideline for Elemental Impurities; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: Regional Public Workshop on ICH Q3D Implementation of Guideline for Elemental Impurities. The purpose of the public workshop is to elaborate key aspects of the ICH Guideline Q3D: Guideline on Elemental Impurities in order facilitate a harmonized interpretation and implementation by industry and regulators. It is not intended to provide additional guidance beyond the scope of Q3D. The meeting will take place on the FDA campus and also be broadcast on the Web allowing participants to join in person or via the Web.

DATES: The public workshop will be held on August 22 and 23, from 9 a.m. to 5 p.m., EST. See the SUPPLEMENTARY INFORMATION section for information on how to register.

ADDRESSES: The public workshop will be held at 10903 New Hampshire Ave., Bldg. 31, rm. 1503B/C, Silver Spring, MD 20993. The entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1176, Silver Spring, MD, 20993, 301-796-4548, email: Amanda.Roache@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The ICH brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. The ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. The ICH Q3D Guideline was developed by the ICH to provide a global policy for limiting elemental impurities qualitatively and quantitatively in drug products and ingredients. Following finalization of this Guideline, an Implementation Working Group was established to develop a comprehensive training program and supporting documents sponsored by ICH to ensure the proper interpretation and effective utilization by industry and regulators alike to enable a harmonized and smooth implementation of Q3D on a global basis.

The U.S. regional workshop is intended to clarify key aspects of ICH Q3D: Guideline on Elemental Impurities by elaborating on those key topics. It will include: (1) A discussion of how to apply Q3D concepts to routes of administration, not addressed in Q3D, (2) justification for elemental impurity levels higher than an established permissible daily exposure (PDE) (3) application of Q3D concepts to determine safe levels of elements not included in Q3D, (4) discussion of the rationale for limits on large volume parenterals, (5) elaboration of the concepts outlined in the Q3D Sections on Risk Assessment and Control of Elemental Impurities and (6) options for converting between PDEs and concentrations.

In addition, case studies may be presented to illustrate the concepts described previously, and frequently asked questions will be discussed. The presentation of the material will follow the modules that are available on the ICH Web site, www.ich.org, and will include time for questions and discussion. Breakout sessions will be provided to discuss key topics and provide feedback to participants. Material will be presented by members of the ICH Q3D Implementation Working Group. The agenda for the workshop will be made available on the internet at http://www.fda.gov/Drugs/NewsEvents/ucm498553.htm.

Registration: If you wish to attend this meeting, visit the following Web site to register: https://www.eventbrite.com/e/regional-public-workshop-on-ich-q3d-implementation-of-guideline-for-elemental-impurities-tickets-25492458630. Please register by August 15, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast on the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Amanda Roache (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Dated: July 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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