Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act—OMB Control Number 0910–0375—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

FDA receives an average of one application for accreditation for third-party review per year. According to FDA's data, the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers. Third-party reviewers are required to keep records of their review of each submission.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	10	26	260	40	10,400
Total					10,424

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews	10	26	260	10	2,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 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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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1486]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Hologic, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of June 17, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad,