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CLIA High Complexity Laboratories

- M. CLIA High Complexity Laboratories will include with reports of the results of the Lyra™ Influenza A Subtype H7N9 Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients.
- N. CLIA High Complexity Laboratories will perform the assay on a bioMerieux NucliSENS® easyMAG® Nucleic Acid Extraction System and an Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with the appropriate software, respectively.
- O. CLIA High Complexity Laboratories will have a process in place for reporting test results to healthcare providers and federal, state, and/or local public health authorities, as appropriate.
- P. CLIA High Complexity Laboratories will collect information on the performance of the assay, and report to Quidel Corporation any suspected occurrence of false positive or false negative results of which CLIA High Complexity laboratories become aware.
- Q. CLIA High Complexity Laboratories will clearly and conspicuously state on reports of the results of the Lyra™ Influenza A Subtype H7N9 Assay that this test is only authorized for the diagnosis of influenza A (H7N9) virus (detected in China in 2013) and not for seasonal influenza A, B, or any other pathogen.

Quidel Corporation and CLIA High Complexity Laboratories

- R. Quidel Corporation and CLIA High Complexity Laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized Lyra™ Influenza A Subtype H7N9 Assay as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.


Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-08706 Filed 4-16-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0331]

Live Case Presentations During Investigational Device Exemption Clinical Trials; Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff.” This guidance is intended, in part, to improve the quality of information submitted by sponsors in an IDE application or supplement to an IDE application and to ensure consistency in the review of those submissions. This draft guidance is intended to clarify FDA’s regulations and policies regarding live case

presentations using unapproved or uncleared investigational devices in the United States. This draft guidance is not final nor is it in effect at this time.

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 July 16, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1651, Silver Spring, MD 20993-0002, 301-796-6563, sheila.brown@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Requests for live case presentations have been submitted to the Agency as multiple supplements to an approved IDE application as either protocol deviations, changes to the investigational plan, or study expansion requests. Live case presentations have not generally been prospectively identified and described as components of the overall study design in original IDE applications.

Although it is expected that very few investigations conducted under an IDE will have the need for live case

presentations, FDA has seen an increase in the number of requests for certain investigations to conduct live case presentations. Live case presentations may increase awareness of the study for potential investigators and facilitate the recruitment of subjects. Increased awareness of the IDE clinical study by other health care professionals resulting from a live case presentation might accelerate enrollment of eligible subjects which, in turn, may lead to new therapies being made available sooner. However, because of concerns related to human subject protection and uncertainty about potential differences between outcomes of subjects participating in live case presentations compared to subjects not participating in live case presentations, this guidance was developed for institutional review boards, review staff, the regulated industry and clinical community.

II. Significance of Guidance

This 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 Agency's current thinking on live case presentations during IDE clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff," may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1736 to identify the guidance you are requesting.

IV. 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 21 CFR part 812 have been approved under OMB control number 0910-0078.

V. 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>.

Dated: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0332]

Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices." National outbreaks of Toxic Anterior Segment Syndrome (TASS) have been associated with single-use intraocular ophthalmic devices (IODs) and single-use intraocular ophthalmic surgical instruments/accessories that are contaminated with endotoxins. These devices can become contaminated as part of the manufacturing, sterilization, or packaging processes. This guidance document provides recommendations for endotoxin limits as well as endotoxin testing to manufacturers and other entities involved in submitting premarket applications (PMAs) or premarket notification submissions (510(k)s) for different categories of IODs