4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0790]

Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff; Food and Drug Administration Decisions for Investigational Device Exemption (IDE) Clinical Investigations; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the Federal Register of Thursday, November, 10, 2011 (76 FR 70151). In the notice, FDA requested comments on the draft guidance that has been developed to promote the initiation of clinical investigations to evaluate the medical devices under FDA's Investigational Device Exemptions (IDE) regulations. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit written or electronic comments and information by March 9, 2012.

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 10, 2011 (76 FR 70151), FDA published a notice announcing the availability of the draft guidance entitled ‘‘FDA Decisions forInvestigational Device Exemption (IDE) Clinical Investigations” and the opening of apublic docket to receive comments on the development of methods to allow a clinical investigation to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. Interested persons were invited to submit comments by February 8, 2012. At this time, the Agency is extending the comment period until March 9, 2012, to continue to receive public comments. Comments submitted to the

docket will assist in promoting timely clinical investigations actions that the Center for Devices and Radiological Health and Center for Biologics Evaluation and Research can consider taking for IDE submissions.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the 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.

Dated: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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