4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1145]

Draft Guidance for Industry on Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the draft guidance for industry entitled "Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products" that appeared in the Federal Register of December 17, 2012 (77 FR 74670). In the document, FDA announced the availability of this draft guidance and explained that the comment period would close on February 15, 2013. The Agency is taking this action to allow interested persons additional time to submit comments.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 18 2013.

ADDRESSES: Submit electronic comments 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In the Federal Register of December 17, 2012 (77 FR 74670), FDA announced the availability of this draft guidance and explained that the comment period would close on February 15, 2013. The Agency is extending the comment period to March 18, 2013, to allow more time for public comments.

This document provides guidance to industry on enrichment strategies that can be used in clinical trials intended to support effectiveness and safety claims in new drug applications and biologics license applications. Similar approaches could be used in clinical trials in earlier phases of drug development. This draft guidance defines and discusses three enrichment strategies: Decreasing heterogeneity, predictive enrichment, and prognostic enrichment. The guidance also discusses general clinical trial design considerations, provides examples of potential clinical trial designs, and discusses regulatory considerations when using enrichment strategies.

II. Submission of 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: January 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-02293 Filed 02/01/2013 at 8:45 am; Publication Date: 02/04/2013]