4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0271]

Availability of Masked and De-identified Non-Summary Safety and Efficacy Data; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice entitled "Availability of Masked and De-identified Non-Summary Safety and Efficacy Data; Request for Comments," which appeared in the Federal Register of June 4, 2013 (78 FR 33421). The Agency is reopening the comment period in response to requests for additional time and to allow interested persons more time to submit comments.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]

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. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., HILL-3110, Silver Spring, MD 20993, 301-796-3603, FAX: 301-431-6351, Nancy.sager@fda.hhs.gov; Stephen

Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210; or Aaliyah Eaves-Leanos, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5435, 301-796-2948, FAX: 301-847-8510, Aaliyah.Eaves-Leanos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 4, 2013 (78 FR 33421), FDA published a request for public comments from interested persons on the proposed availability of de-identified and masked data derived from medical product applications. In that notice, FDA requested comments by August 5, 2013, on the following topics: (1) What factors should be considered in masking study data (e.g., data fields from regulatory submissions to remove or modify, number of different products to pool within a product class); (2) what limitations, if any, should there be on the Agency's ability to make available the masked data as described previously; (3) are there any additional factors FDA should consider in de-identifying data in addition to FDA's requirement to remove any names and other information (e.g., birth date, death date, local geographic information, contact information) that would identify patients or research subjects before disclosing information; (4) would regulatory changes facilitate implementation of such a proposal, and if so, what changes would be most useful; and (5) which situations do you believe disclosing masked data would be most useful to advance public health?

The comment period was 60 days, but the Agency has received requests for an additional 30 days for submitting comments. Each request conveyed concern that the 60-day comment period did not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the requests and will reopen the comment period for an additional 30 days, thus extending the comment period to [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

II. How to Submit 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: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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