



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1461]

Rare Pediatric Disease Priority Review Vouchers; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of availability (NOA) that appeared in the Federal Register of November 17, 2014. In the NOA, FDA requested comments on the Agency's implementation of the Rare Pediatric Disease Priority Review Vouchers Program. This action will allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the NOA published November 17, 2014 (79 FR 68451). Submit either electronic or written comments by February 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002; or Office of Orphan Products Development, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5295, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist

the office that will be processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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.

FOR FURTHER INFORMATION CONTACT: Henry Startzman III, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5295, Silver Spring, MD 20993-0002, 301-796-8660.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of November 17, 2014, FDA published a NOA with a 60-day comment period to request comments on FDA's implementation of the Rare Pediatric Disease Priority Review Vouchers Draft Guidance. Comments on the draft guidance will inform FDA's drafting of its final guidance for this program.

The Agency has recognized a discrepancy between the 90-day comment period included in the draft guidance and the 60-day comment period written in the November 17, 2014, NOA. Thus, it is publishing this NOA to extend the comment period cited in the previous NOA by 30 days.

The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying drafting of the final guidance on these important issues.

## II. Request for 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: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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