This document is scheduled to be published in the
Federal Register on 09/04/2014 and available online at
http://federalregister.gov/a/2014-21051, and on **FDsys.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1264]

Submission of a Proposed Draft Guidance for Industry on Developing Drugs for Treatment of Duchenne Muscular Dystrophy; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to discuss issues related to developing drugs for Duchenne muscular dystrophy (DMD). During a public-private policy forum for DMD on December 12, 2013, FDA agreed that Parent Project Muscular Dystrophy (PPMD) and other interested parties in the DMD community could submit for FDA consideration a proposal for a draft guidance for industry on developing drugs for DMD. That proposed draft guidance was submitted to FDA on June 25, 2014. FDA values the guidance provided by the DMD community and is posting the document to seek additional guidance and public comment.

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

ADDRESSES: Submit written requests for single copies of the proposed draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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.

Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the proposed draft guidance document.

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 in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Colleen LoCicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4242, Silver Spring, MD 20993-0002, 301-796-1114, colleen.locicero@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Comments

FDA invites comment on all matters relating to topics for consideration regarding DMD drug development. This request is not limited to comments on the proposal described in the submission by PPMD.

Interested persons may submit either electronic comments 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.

II. Electronic Access

Persons with access to the Internet may obtain the proposed draft guidance document at http://www.regulations.gov.

Dated: August 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21051 Filed 09/03/2014 at 8:45 am; Publication Date: 09/04/2014]