ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Program Performance Report (PPR)	56	1	138	7,728
Estimated Total Annual Burden Hours:	.....	.....	.....	7,728

Dated: June 3, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015–14051 Filed 6–9–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1884]

Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of X-linked Duchenne muscular dystrophy (DMD) and related dystrophinopathies.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 10, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment.''

DMD and other dystrophinopathies result from genetic mutations in the dystrophin gene that decrease levels of dystrophin and/or cause dysfunction of the dystrophin protein, leading to muscle degeneration, including cardiac and respiratory muscles, and greatly decreased life expectancy. There remains a high level unmet medical need for effective drug treatments for DMD and other dystrophinopathies. This draft guidance addresses FDA's current thinking regarding the clinical development program and clinical trial designs for drugs to support an indication for the treatment of dystrophinopathies. Development of this draft guidance was greatly facilitated by the efforts of Parent Project Muscular Dystrophy to coordinate a consortium of stakeholders including patients, parents and caregivers, clinicians, academic experts, and industry representatives in producing a proposed draft guidance with extensive background information about DMD. That stakeholder proposal was submitted to FDA and made available for comment through a **Federal Register** notice seeking public comment. The comments received were also considered in writing this draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs for the treatment of DMD. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14100 Filed 6–9–15; 8:45 am]

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