TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.120(b), Number of submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
312.120(c), Number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
312.130, Number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.34	470	8	3,760
312.310(b) and 312.305(b), Number of submissions related to expanded access and treatment of an individual patient	78	1.08	84	8	672
312.310(d), Number of submissions related to emergency use of an investigational new drug	76	2.76	210	16	3,360
312.315(c) and 312.305(b), Number of submissions related to expanded access and treatment of an intermediate-size patient population	9	1	9	120	1,080
312.320(b), Number of submissions related to a treatment IND or treatment protocol	1	1	1	300	300
Total					3,254,062

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
312.52(a), Sponsor records for the transfer of obligations to a contract research organization	75	1.40	105	2	210
312.57, Sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interests	335	2.70	904	100	90,400
312.62(a), Investigator recordkeeping of the disposition of drugs	453	1	453	40	18,120
312.62(b), Investigator recordkeeping of case histories of individuals	453	1	453	40	18,120
312.160(a)(3), Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	111	1.40	155	*0.50	78
312.160(c), Shipper records of alternative disposition of unused drugs	111	1.40	155	*0.50	78
Total					127,006

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* Thirty (30) minutes.

Dated: February 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–04379 Filed 3–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0430]

Measuring Dystrophin in Dystrophinopathy Patients and Interpreting the Data; Public Scientific Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public scientific workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public scientific workshop to discuss dystrophin protein quantification methodologies for human tissue. This workshop is being cosponsored by the National Institutes of Health (NIH). The purpose of the workshop is to discuss currently available methodologies and to identify scientific knowledge gaps and opportunities for improving dystrophin protein detection in the context of drug development. The intended audiences for this workshop are scientists and clinicians involved in the acquisition, measurement, and analysis of proteins associated with Duchenne Muscular Dystrophy (DMD).

DATES: *Dates and Time:* The scientific workshop will be held on March 20, 2015, from 8:30 a.m. to 5:30 p.m.

ADDRESSES: The scientific workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3519, *mary.gross@fda.hhs.gov;* or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3515, *georgiann.ienzi@fda.hhs.gov.*

If you need special accommodations due to a disability, contact Mary Gross or Georgiann Ienzi at least 7 days in advance.

Registration: The scientific workshop is free and seating will be on a first-come, first-served basis. It may be necessary to limit both the number of attendees from individual organizations and the total number of attendees based on space limitations. Email registrations should be sent to *Dystrophin_Workshop@fda.hhs.gov* by March 17, 2015. If you cannot attend in person, the meeting will be Webcast live. Information about how to access the Webcast will be located at: *http://www.fda.gov/Drugs/NewsEvents/ucm432429.htm.*

Comments and Meeting Summary: Submit electronic comments to *http://www.regulations.gov* by May 20, 2015. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please identify your comments with the docket number found in brackets in the heading of this document. It is only necessary to send one set of comments. 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.*

A summary of the scientific workshop's highlights will be made available for review at the Division of Dockets Management and at *http://www.regulations.gov.* You may submit a request to obtain a hard copy by sending a request to the Division of Freedom of Information (ELEM–1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: FDA and NIH are cosponsoring this scientific workshop to discuss current methodologies being used in drug development and scientific research for DMD. Recent scientific advances present an opportunity for the development and validation of robust methods for the objective, reliable, and quantitative measurement of DMD-associated proteins.

I. Background

Dystrophinopathies result from genetic mutations in the dystrophin gene that decrease dystrophin protein expression levels and result in altered dystrophin function. These changes can lead to muscle degeneration and, in many patients, downstream pathologies including inflammation and fibrosis that interfere with muscle regeneration, loss of movement, orthopedic complications, and ultimately respiratory and cardiac failure.

II. Scope of the Scientific Workshop

The workshop will include sessions which will focus on current technologies used in the detection of dystrophin. Presentations will provide overviews of the technologies (including limitations, detection sensitivities, linearity, and reproducibility). A panel discussion will help identify development challenges for each method. Muscle biopsy collection, sample handling, reference materials, and image analysis will also be discussed.

FDA will post the agenda and other background material approximately 2 days before the public scientific workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm432429.htm.*

Dated: February 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–04384 Filed 3–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pediatric Neurocognitive Workshop; Advancing the Development of Pediatric Therapeutics Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Division of Gastroenterology and Inborn Errors Products Division and Division of Pediatric and Maternal Health in the Center for Drug Evaluation and Research, and the Office of Pediatric Therapeutics in the Office of the Commissioner are announcing a 2-day public workshop. Day 1 of the workshop is entitled ''Assessment of Neurocognitive Outcomes in the Inborn Errors of Metabolism''. Day 2 of the workshop is entitled, ''Advancing the Development of Pediatric Therapeutics: Assessment of Pediatric Neurocognitive Outcomes''. The purpose of this 2-day workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of neurocognitive outcomes in pediatric patients.

DATES: The public workshop will be held on April 16 and 17, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held in the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: For questions regarding Day 1 of the workshop, contact Richard (Wes) Ishihara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0069, *richard.ishihara@fda.hhs.gov.*

For questions regarding Day 2 of the workshop, contact Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug