TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Registered licensed mixer-feeders] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.42(b) through (b)(8)	100	260	26,000	0.15 (9 minutes)	3,900
225.58(c) through (d)	100	36	3,600	0.50 (30 minutes)	1,800
225.80(b) (2)	100	48	4,800	0.12 (7 minutes)	576
225.102(b)(1) through (b)(5)	100	260	26,000	0.40 (24 minutes)	10,400
Total					16,676

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Nonregistered unlicensed commercial feed mills] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.142	4,186	4	16,744	1	16,744
225.158	4,186	1	4,186	4	16,744
225.180	4,186	96	401,856	0.12 (7 minutes)	48,223
225.202	4,186	260	1,088,360	0.65 (39 minutes)	707,434
Total					789,145

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Nonregistered unlicensed mixer-feeders] [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.142	3,400	4	13,600	1	13,600
225.158	3,400	1	3,400	4	13,600
225.180	3,400	32	108,800	0.12 (7 minutes)	13,056
225.202	3,400	260	884,000	0.33 (20 minutes)	291,720
Total					331,976

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

The estimate of time required for record preparation and maintenance is based on Agency communications with industry. Other information needed to finally calculate the total burden hours (*i.e.,* number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from Agency records and experience.

Dated: October 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25041 Filed 10–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Substitutability of Generic Drugs: Perceptions and Reality; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Johns Hopkins University Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop entitled ''Substitutability of Generic Drugs: Perceptions and Reality.'' The objective of this workshop is to discuss FDA and industry practices related to postmarket surveillance of generic drugs, postmarket generic drug research activities, public perceptions of generic drug quality and effectiveness, and verification of therapeutic equivalence of generic drugs. This workshop will also give stakeholders, including scientists from government, academia, and industry, patient advocacy groups, clinicians, pharmacists, and the general public an opportunity to provide their insights on future research needs in postmarket surveillance of generic drugs.

DATES: The public workshop will be held on November 18, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting 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: Audrey Thomas, Office of Regulatory Science and Innovation, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4220, Silver Spring, MD 20993–0002, 301–796–3520, *Audrey.Thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide an opportunity for stakeholders, including scientists from government, academia, and industry, patient advocacy groups, clinicians, pharmacists, and the general public to discuss marketed generic drugs. Generic drugs account for 88 percent of prescriptions in the United States. In light of the significant contributions of generic drugs to public health, it is important that tools are developed to monitor marketed generic drugs to ensure that they have the same safety and effectiveness as their reference listed drug. Specifically, this workshop will include presentations on: (1) Current generic drug surveillance practices at FDA and in industry, (2) public perception of generic drug quality and effectiveness, (3) generic drug substitution studies in patients, and (4) development of methods and tools to conduct postmarket surveillance of generic drugs. The workshop will include four panel sessions for interaction and discussion among the speakers and attendees.

Agenda: The agenda is available at *http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm521545.htm.*

Registration: There is no registration fee to attend this public workshop. Seats are limited and registration will be on a first-come, first-served basis. Advance registration is required and is online only at *http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm521545.htm.* There will be no day-of, onsite registration.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. There is no registration fee for access to the workshop via the Webcast, but registration is still required. Information regarding registration and access to the Webcast link is available at *http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm521545.htm.* If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified these Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations while at FDA's White Oak Campus due to a disability, please contact Shari Solomon at *Shari.Solomon@fda.hhs.gov* at least 7 days in advance.

Dated: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25004 Filed 10–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that EXONDYS 51 (eteplirsen), manufactured by Sarepta Therapeutics, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4842, FAX: 301–796–9858, email: *larry.bauer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that EXONDYS 51 (eteplirsen), manufactured by Sarepta Therapeutics, meets the criteria for a priority review voucher. EXONDYS 51 (eteplirsen) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about EXONDYS 51 (eteplirsen) go to the ''Drugs@FDA'' Web site at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*

Dated: October 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24947 Filed 10–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0901]

Abbreviated New Drug Application Submissions—Prior Approval Supplements Under Generic Drug User Fee Amendments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''ANDA Submissions—Prior Approval Supplements Under GDUFA.'' The Generic Drug User Fee Amendments of 2012 (GDUFA) enables FDA to assess user fees to fund critical and measurable improvements to FDA's generic drugs program. This guidance is intended to assist applicants preparing to submit to FDA prior approval supplements (PASs) and amendments to PASs for abbreviated new drug applications (ANDAs). It describes FDA's performance metric goals for PASs and clarifies how FDA will handle a PAS