### Table 2—Estimated Annual Recordkeeping Burden

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

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

### Table 3—Estimated Annual Recordkeeping Burden

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

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

### Table 4—Estimated Annual Recordkeeping Burden

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

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

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**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
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**

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**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 drug product applications that meet certain criteria. FDA has determined that EXONDYS 51 (etepilisen), manufactured by Sarepta Therapeutics, meets the criteria for a priority review voucher. EXONDYS 51 (etepilisen) 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/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm. For further information about EXONDYS 51 (etepilisen) 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**

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**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.