### Supplementary Information

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2021–N–0492]

**Watson Laboratories, Inc. et al.; Withdrawal of Approval of 36 Abbreviated New Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 36 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of July 26, 2021.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, Martha.Nguyen@fda.hhs.gov.

**TABLE 2—Estimated Annual Recordkeeping Burden**

<table>
<thead>
<tr>
<th>21 CFR Section; Activity</th>
<th>Number of Recordkeepers</th>
<th>Number of Records per Recordkeeper</th>
<th>Total Annual Records</th>
<th>Average Burden per Recordkeeping</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart C: Sales Restrictions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>203.23(a) and (b); returns</td>
<td>2,200</td>
<td>71.9909</td>
<td>158,380</td>
<td>0.25 (15 minutes)</td>
<td>39,595</td>
</tr>
<tr>
<td>203.23(c); documentation of storage of returns</td>
<td>2,200</td>
<td>71.9909</td>
<td>158,380</td>
<td>0.08 (~6 minutes)</td>
<td>12,670</td>
</tr>
<tr>
<td>Subpart D: Samples</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>203.30–203.39; documentation regarding sample distributions</td>
<td>140</td>
<td>202</td>
<td>28,280</td>
<td>−0.07–0.08 (~4–5 minutes)</td>
<td>2,121</td>
</tr>
<tr>
<td>Total</td>
<td>...............................................</td>
<td>........................................</td>
<td>345,040</td>
<td>..................................</td>
<td>54,386</td>
</tr>
</tbody>
</table>

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

2 Rounded to the nearest whole number.

Based on a review of Agency data, we assume 2,200 respondents may incur burden resulting from the information collection activity associated with the requirements in § 203.23(a) through (c). A total of 140 pharmaceutical companies have submitted information to the Agency on drug sample distribution under part 203. Those same respondents also have recordkeeping requirements under part 203. Our estimate of the burden of the average requirements per recordkeeping reflects a cumulative average to cover all applicable requirements. Since our last request for OMB approval, we have adjusted our estimate of the overall burden downward to reflect a decrease of 2,567,713 hours and 64,432,232 records annually. We attribute this adjustment to a more accurate reflection of the number of respondents to the information collection and clarification that burden attributable to requirements of the Drug Quality and Security Act are not included in this information collection.

Dated: June 21, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13597 Filed 6–24–21; 8:45 am]

BILLING CODE 4164–01–P
Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 26, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on July 26, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 21, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be held as a virtual meeting and is open to the public.

Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (http://videocast.nih.gov/).

Name of Committee: Interagency Autism Coordinating Committee.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (www.iacc.hhs.gov) prior to the meeting. Pre-registration is recommended.

Deadlines: Written/Virtual Public Comment Due Date: Friday, July 2, 2021, by 8:45 am ET.

AGENDA

I. Introduction

II. Administrative Business

III. Interagency Autism Coordinating Committee (IACC) Business

IV. Interagency Workgroups

V. Next Steps

VI. Other Issues

VII. Adjourn