TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping	Total hours
Subpart C: Sales restrictions					
203.23(a) and (b); returns	2,200	71.9909	158,380	0.25 (15 minutes)	39,595
203.23(c); documentation of storage of returns.	2,200	71.9909	158,380	0.08 (~6 minutes)	12,670
Subpart D: Samples					
203.30–203.39; documentation regarding sample distributions.	140	202	28,280	~.07–.08 (~4–5 minutes)	2,121
Total			345,040		54,386

[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 burden 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

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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of July 26, 2021.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

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 062142	Doxycycline Hyclate Capsules, Equivalent to (EQ) 50 milligrams (mg) base and EQ 200 mg base.	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 062497	Doxycycline Hyclate Capsules, EQ 50 mg base and EQ 100 mg base.	Teva Pharmaceuticals USA, Inc. 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 065152	Cephalexin Capsules, EQ 250 mg base and EQ 500 mg base.	Yung Shin Pharmaceutical Ind. Co. Ltd., authorized U.S. agent, Carlsbad Technology, Inc./Simon Law, 5922 Farnsworth Ct., Suite 101, Carlsbad, CA 92008.
ANDA 070550	Propranolol Hydrochloride (HCl) Tablets, 40 mg	Watson Laboratories, Inc.
ANDA 070551	Propranolol HCl Tablets, 80 mg	Do.
ANDA 070943	Oxazepam Capsules, 10 mg	IVAX Pharmaceuticals Inc. (an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 070945	Oxazepam Capsules, 30 mg	Do.
ANDA 071446	Temazepam Capsules, 15 mg	Watson Laboratories, Inc.
ANDA 071447	Temazepam Capsules, 30 mg	Do.
ANDA 072952	Oxazepam Capsules, 10 mg	Do.
ANDA 073092	Baclofen Tablets, 10 mg	Do.

Application No.	Drug	Applicant
ANDA 074400	Diflunisal Tablets, 250 mg and 500 mg	Do.
ANDA 074432	Diclofenac Sodium Delayed Release Tablets, 50 mg and 75 mg.	Pliva, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 074460	Piroxicam Capsules, 10 mg and 20 mg	Watson Laboratories, Inc.
ANDA 074585	Indapamide Tablets, 1.25 mg and 2.5 mg	Do.
ANDA 074698	Baclofen Tablets, 10 mg and 20 mg	Do.
ANDA 074711	Mexiletine HCl Capsules, 150 mg, 200 mg and 250 mg	Do.
ANDA 074723	Diclofenac Sodium Delayed Release Tablets, 50 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074852	Diltiazem HCl Extended Release Capsules, 120 mg, 180 mg, and 240 mg.	Actavis Laboratories FL, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 074865	Mexiletine HCl Capsules, 150 mg, 200 mg, and 250 mg	Watson Laboratories, Inc.
ANDA 074870	Acyclovir Tablets, 400 mg and 800 mg	Actavis Elizabeth LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 075101	Acyclovir Capsules, 200 mg	Watson Laboratories, Inc.
ANDA 076022	Fluoxetine HCl Capsules, EQ 10 mg base and EQ 20 mg base.	Carlsbad Technology, Inc., 5922 Farnsworth Ct., Carlsbad, CA 92008.
ANDA 078345	Prednisolone Sodium Phosphate Solution, EQ 15 mg base/5 milliliters (mL).	Amneal Pharmaceuticals, 85 Adams Ave., Hauppauge, NY 11788.
ANDA 080521	Isoniazid Tablets, 300 mg	Watson Laboratories, Inc.
ANDA 086537	Nitroglycerin Controlled-Release Capsules, 6.5 mg	Lumara Health, Inc., 1100 Winter St., Suite 3000, Waltham, MA 02451.
ANDA 086889	Disulfiram Tablets, 250 mg	Watson Laboratories, Inc.
ANDA 086890	Disulfiram Tablets, 500 mg	Watson Laboratories, Inc.
ANDA 087975	Nitroglycerin Controlled-Release Capsules, 2.5 mg	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 087976	Nitroglycerin Controlled-Release Capsules, 6.5 mg	Do.
ANDA 088509	Nitroglycerin Controlled-Release Capsules, 9 mg	Do.
ANDA 090833	Carbidopa/Levodopa and Entacapone Tablets, 18.75 mg/200 mg/75 mg, 25 mg/200 mg/100 mg, 31.25 mg/200 mg/125 mg, 37.5 mg/200 mg/150 mg, and 50 mg/200 mg/200 mg.	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053.
ANDA 200771	Irinotecan HCl Injection, 40 mg/2 mL (20 mg/mL) and 100 mg/5 mL (20 mg/mL).	Heritage Pharmaceuticals Inc. d/b/a/Avet Pharmaceuticals Inc. U.S. Agent for Emcure Pharmaceuticals Limited, One Tower Center Blvd., East Brunswick, NJ 08816.
ANDA 202063	Gemcitabine HCl for Injection, EQ 200 mg base/vial; EQ 1 gram base/vial.	Do.
ANDA 204437	Sodium Fluoride 18 Injection, 10–200 millicurie (mCi)/mL	UCSF Radiopharmaceutical Facility, 185 Berry St., Suite 350, San Francisco, CA 94107.
ANDA 208444	Choline C–11 Injection, 4–33.1 mCi/mL	Do.

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.

[FR Doc. 2021–13593 Filed 6–24–21; 8:45 am]

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. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the 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.

Date: July 21–22, 2021.

Time: Wednesday, July 21, 2021—1:00 p.m. to 4:00 p.m. ET, *https://videocast.nih.gov/watch=42326;* Thursday, July 22, 2021—2:00 p.m. to 5:00 p.m. ET, *https://videocast.nih.gov/watch=42327.*

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

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