DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0525]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 26, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements—21 CFR Part 203

OMB Control Number 0910–0435—Extension

This information collection supports FDA regulations codified at part 203 (21 CFR part 203) implementing the Prescription Drug Marketing Act of 1987 (PDMA) and the Prescription Drug Amendments of 1992. The Federal Food, Drug, and Cosmetic Act, as amended by the PDMA, establishes requirements for the following:

- Reimportation of prescription drugs.
- The sale, purchase, or trade of or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or health care entities or donated to charitable organizations.
- The distribution of prescription drug samples by mail, common carrier, or another means of distribution.
- Applications for reimportation to provide emergency medical care.
- An appeal from an adverse decision by the district office.
- Drug sample storage and handling.
- Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.
- Donation of drug samples to charitable institutions.

The PDMA was enacted, in part, because insufficient safeguards existed over the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs. The PDMA is intended to ensure that drug products purchased by consumers are safe and effective, and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

The applicable regulations in part 203 include reporting and recordkeeping requirements intended to help achieve the following goals: (1) To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care; (2) to ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) to limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other healthcare entities at the request of a licensed or authorized practitioner; (4) to require licensed or authorized practitioners to request prescription drug samples in writing; (5) to mandate storage, handling, and recordkeeping requirements for prescription drug samples; and (6) to prohibit, with certain exceptions, the sale, purchase, or trade, or the offer to sell, purchase, or trade, of prescription drugs that were purchased by hospitals or other healthcare entities or that were donated or supplied at a reduced price to a charitable organization.

In the **Federal Register** of March 12, 2021 (86 FR 14128), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
203.11; reimportation applications	1	1	1	0.5 (30 minutes)	[2] 1
203.37(a); falsification of records	140	21.4	3,000	0.25 (15 minutes)	750
203.37(b); loss or theft of samples ...	140	178.57	25,000	0.25 (15 minutes)	6,250
203.37(c); conviction of representatives.	1	1	1	1	1
203.37(d); contact person	20	1	20	0.25 (15 minutes)	5
Total	.....	.....	28,022	.....	7,007

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest whole number.

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]

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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.