TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

PHS guideline section	Description	21 CFR section (unless otherwise stated)
3.1.1 and 3.1.6	Document well-characterized health history and lineage of source animals..	312.23(a)(7)(a) and 211.84.
3.1.8	Registration with and import permit from the Centers for Disease Control and Prevention..	42 CFR 71.53.
3.2.2	Document collaboration with accredited microbiology labs	312.52.
3.2.3	Procedures to ensure the humane care of animals	9 CFR parts 1, 2, and 3 and PHS Policy [1].
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC) Guide.	AAALAC International Rules of Accreditation [2] and NRC Guide [3].
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122.
3.2.6	Animal facility SOPs	PHS Policy [1].
3.3.3	Validate assay methods	211.160(a).
3.6.1	Procurement and processing of xenografts using documented aseptic conditions.	211.100 and 211.122.
3.6.2	Develop, implement, and enforce SOPs for procurement and screening processes.	211.84(d) and 211.122(c).
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient.	312.32(c).
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6).
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 yrs.); investigator case histories (2 yrs. after investigation is discontinued).	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c).
4.1.2	Sponsor to justify amount and type of reserve samples	211.122.
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a).
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection.	312.32.
4.2.2.1	Document collaborations (transfer of obligation)	312.52.
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly).	312.50.
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b).

[1] The ''Public Health Service Policy on Humane Care and Use of Laboratory Animals'' (*https://olaw.nih.gov/policies-laws/phs-policy.htm*).
[2] AAALAC International Rules of Accreditation (*https://www.aaalac.org/accreditation-program/rules-of-accreditation/*).
[3] The NRC's ''Guide for the Care and Use of Laboratory Animals.''

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate other than to adjust total burden hours by one hour, from 60 to 59 total burden hours, to address an inadvertent error in disclosure burden in the previous submissions to OMB.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08737 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0413]

Baxter Healthcare Corporation, et al.; Withdrawal of Approval of 14 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, Health and Human Service (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 14 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 May 25, 2022.

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 075695	Butorphanol Tartrate Injection, 1 milligram (mg)/milliliter (mL), and 2 mg/mL.	Baxter Healthcare Corporation, One Baxter Pkwy., Deerfield, IL 60015.
ANDA 075697	Butorphanol Tartrate Injection, 2 mg/mL	Do.
ANDA 077290	Oxycodone Hydrochloride (HCl) Tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg.	Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044.
ANDA 078564	Granisetron HCl Injection, Equivalent to (EQ) 1 mg base/mL (EQ 1 mg base/mL).	Morton Grove Pharmaceuticals Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 078565	Granisetron HCl Injection, EQ 4 mg base/4 mL (EQ 1 mg base/mL).	Do.
ANDA 078566	Granisetron HCl Injection, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL).	Do.
ANDA 088342	Fluoxymesterone Tablets, 10 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 202032	Lamivudine Tablets, 150 mg and 300 mg	Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 205322	Efavirenz Tablets, 600 mg	Do.
ANDA 205690	Choline C–11 Injection, 4–100 millicurie/mL	University of Texas MD Anderson Cancer Center, 1881 East Rd., Unit 1903, Houston, TX 77054.
ANDA 207653	Rosuvastatin Calcium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base.	SciRegs International, Inc., 6333 Summercrest Dr., Columbia, MD 21045.
ANDA 208199	Azelastine HCl Metered Spray, 0.2055 mg/spray	Amneal Pharmaceuticals LLC, 50 Horseblock Rd., Brookhaven, NY 11719.
ANDA 210032	Azelastine HCl Metered Spray, 0.2055 mg/spray	Akorn Operating Company LLC, 1925 West Field Ct., Suite 300, Lake Forest, IL 60045.
ANDA 211461	Bosentan Tablets, 62.5 mg and 125 mg	Syneos Health Global Headquarters, 1030 Sync St., Third Floor, Morrisville, NC 27560.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 25, 2022. 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 May 25, 2022 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: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08744 Filed 4–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 25, 2022.

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 0910–0482. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Export Notification and Recordkeeping Requirements

OMB Control Number 0910–0482—Extension

Sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381 and 382) charge the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification