Application No.	Drug	Applicant
NDA 007959	Tensilon (edrophonium chloride) Injection, 10 milligrams (mg)/milliliter (mL). Tensilon Preservative Free (edrophonium chloride) Injection, 10 mg/mL.	PAI Holdings, LLC dba Pharmaceutical Associates, Inc., 1700 Perimeter Rd., Greenville, SC 29605.
NDA 009900	Cortef (hydrocortisone cypionate) Oral Suspension, Equivalent to (EQ) 10 mg base/5 mL.	Pharmacia and Upjohn Co., 66 Hudson Blvd. East, New York, NY 10001.
NDA 015923	Haldol (haloperidol lactate) Injection, EQ 5 mg base/mL	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, Raritan, NJ 08869.
NDA 017090	Tofranil-PM (imipramine pamoate) Capsules, EQ 75 mg hydrochloride (HCl), EQ 100 mg HCl, EQ 125 mg HCl, and EQ 150 mg HCl.	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119.
NDA 018309	Topicort LP (desoximetasone) Emollient Cream, 0.05%	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
NDA 018401	Buprenex (buprenorphine HCl) Injection, EQ 0.3 mg base/mL	Indivior Inc., 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235.
NDA 019201	Voltaren (diclofenac sodium) Delayed-Release Tablets, 25 mg, 50 mg, and 75 mg.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 019425	Trandate (labetalol HCl) Injection, 5 mg/mL	Sebela Ireland Limited, c/o Sebela Pharmaceuticals Inc., 645 Hembree Pkwy., Suite 1, Roswell, GA 30076.
NDA 020142	Cataflam (diclofenac potassium) Tablets, 25 mg and 50 mg ..	Novartis Pharmaceuticals Corp.
NDA 020254	Voltaren XR (diclofenac sodium) Extended-Release Tablets, 100 mg.	Do.
NDA 020631	Morphine Sulfate Injection, 1 mg/mL and 2 mg/mL	SpecGx LLC.
NDA 020768	Zomig (zolmitriptan) Tablets, 2.5 mg and 5 mg	iPR Pharmaceuticals, Inc., c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.
NDA 020897	Ditropan XL (oxybutynin chloride) Extended-Release Tablets, 5 mg, 10 mg, and 15 mg.	Janssen Pharmaceuticals, Inc.
NDA 020945	Norvir (ritonavir) Capsules, 100 mg	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064.
NDA 021226	Kaletra (lopinavir/ritonavir) Capsules, 133.3 mg/33.3 mg	Do.
NDA 021231	Zomig-ZMT (zolmitriptan) Orally Disintegrating Tablets, 2.5 mg and 5 mg.	iPR Pharmaceuticals, Inc., c/o AstraZeneca Pharmaceuticals LP.
NDA 021360	Sustiva (efavirenz) Tablets, 300 mg and 600 mg	Bristol-Myers Squibb Company, P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 022484	Onmel (itraconazole) Tablets, 200 mg	Sebela Ireland Limited, c/o Sebela Pharmaceuticals Inc.
NDA 050679	Maxipime (cefepime HCl) for Injection, EQ 500 mg base/vial, EQ 1 gram base/vial, and EQ 2 gram base/vial.	Hospira Inc, 275 North Field Dr., Bldg. H1–3S, Lake Forest, IL 60045.
NDA 203696	Lupaneta Pack (leuprolide acetate injection and norethindrone acetate Tablets), 3.75 mg/vial;5 mg and 11.25 mg/vial;5 mg.	AbbVie Endocrinology Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 206302	Byvalson (nebivolol HCl/valsartan) Tablets, EQ 5 mg base/80 mg.	AbbVie Inc.
NDA 208042	Cassipa (buprenorphine HCl/naloxone HCl) Sublingual Film, EQ 16 mg base/EQ 4 mg base.	Teva Pharmaceuticals USA, Inc., 577 Chipeta Way, Salt Lake City, UT 84108.
NDA 208437	Lonhala Magnair Kit (glycopyrrolate) Inhalation Solution, 25 microgram/mL.	Sumitomo Pharma America, Inc., 84 Waterford Dr., Marlborough, MA 01752.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 23, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on May 23, 2024, 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 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08657 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0946]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; 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 the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on the FDA's website entitled ''Postmarketing Requirements and Commitments: Reports'' (*https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/ucm064436.htm*).

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants are required to, or have committed to, conduct and for which annual status reports have been submitted. Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drug products and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application, as applicable. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2022 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year 2022 (*i.e.,* as of September 30, 2022). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) the number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year (FY) of establishment [2] (FY2016 to FY2022) for PMRs and PMCs open at the end of FY2022, or those closed within FY2022. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.html.*

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08649 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1055]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic clearance to collect information to support social and behavioral research used by FDA about drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by June 24, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 24, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.