10. Title: Medicaid Extended Postpartum Coverage and Continuous Eligibility for Children

Type of Request: Extension of a currently approved collection.

CMS ID Number: CMS–10434 #77.

OMB Control Number: 0938–1188.

eRulemaking Docket ID Number: CMS–2023–0088.

Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0088.

For Policy Related Questions, Contact: Alexa Turner at 410–786–8823.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–08658 Filed 4–22–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Community Services Block Grant (CSBG) Model Tribal Plan and Application (New Collection)

AGENCY: Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Community Services (OCS), Administration for Children and Families (ACF), requests an approval of the Community Services Block Grant (CSBG) Model Tribal Plan.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 677 of the CSBG Act requires Indian tribes or tribal organizations to submit an application and plan (CSBG Model Tribal Plan). The CSBG Model Tribal Plan must meet statutory requirements prior to OCS awarding CSBG tribal grant recipients with CSBG funds. Tribal grant recipients have the option to submit a detailed plan annually or biannually. Tribal grant recipients that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur. The CSBG Model Tribal Plan has been used in previous years without OMB approval. To come into compliance with the PRA, ACF is submitting the CSBG Model Tribal Plan as a new request to OMB.

Respondents: Tribal grant recipients (*tribes and tribal organizations)*

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
CSBG Model Tribal Plan	66	1	10	660

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 677, Pub. L. 105–285, 112 Stat. 2742 (42 U.S.C. 9911)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–08668 Filed 4–22–24; 8:45 am]

BILLING CODE 4184–27–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1786]

PAI Holdings, LLC DBA Pharmaceutical Associates, Inc., et al.; Withdrawal of Approval of 23 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 new drug applications (NDAs) 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 23, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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 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
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*).