requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR reimburses, to the extent of available appropriations, certain non-federal costs for the provision of cash and medical assistance (CMA) to refugees, along with allowable expenses for the administration of the refugee resettlement program at the state level. States and Replacement Designees currently submit the ORR–2 Quarterly Report on Expenditures and Obligations, which provides aggregate expenditure and obligation data. The ORR–2 collects expenditures and obligations data separately for each of the four following CMA program components: refugee cash assistance, refugee medical assistance, CMA administration, and services for unaccompanied minors. This breakdown of financial status data allows ORR to track program expenditures in greater detail to anticipate any funding issues and to meet the requirements of ORR regulations at CFR 400.211 to collect these data for use in estimating future costs of the refugee resettlement program. ORR must implement the methodology at CFR 400.211 each year after receipt of its annual appropriation to ensure that appropriated funds will be adequate for reimbursement to states of the costs for assistance provided to entering refugees. The estimating methodology prescribed in the regulations requires the use of actual past costs by program component. If the methodology indicates that appropriated funds are inadequate, ORR must take steps to reduce federal expenses, such as by limiting the number of months of eligibility for Refugee Cash Assistance and Refugee Medical Assistance. The ORR–2 is a single-page financial report that allows ORR to collect the necessary data to ensure that funds are adequate for the projected need and thereby meet the requirements of both the Refugee Act and ORR regulations.

Respondents: State governments and Replacement Designees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
ORR–2, Cash and Medical Assistance Program, Quarterly Report on Expenditures and Obligations	63	4	1.5	378

Estimated Total Annual Burden Hours: 378.

Authority: 8 U.S.C. 1522 Sec. 412 and 8 U.S.C. 524 (Title IV), Sec. 414.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–17078 Filed 8–8–22; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1694]

Determination That AVC (Sulfanilamide) Vaginal Cream, 15%, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 006530	AVC	Sulfanilamide	15%	Cream; Vaginal	Mylan Specialty LP.
NDA 007936	SELSUN	Selenium Sulfide	2.5%	Lotion/Shampoo; Topical	Chattem, Inc.
NDA 008816	XYLOCAINE	Lidocaine Hydrochloride	2%	Jelly; Topical	Akorn.
NDA 009218	COUMADIN	Warfarin Sodium	1 Milligram (mg)	Tablet; Oral	Bristol Myers Squibb.
NDA 012806	CORDRAN SP	Flurandrenolide	0.025%	Cream; Topical	Almirall.
NDA 016647	QUINAGLUTE	Quinidine Gluconate	324 mg	Tablet, Extended Release; Oral.	Bayer Healthcare.
NDA 017386	ZAROXOLYN	Metolazone	2.5 mg; 5 mg; 10 mg	Tablet; Oral	Lannett Co., Inc.
NDA 017531	TIGAN	Trimethobenzamide Hydrochloride.	300 mg	Capsule; Oral	King Pharms LLC.
NDA 018081	DEPAKENE	Valproic Acid	250 mg	Capsule; Oral	AbbVie Inc.
NDA 018281	TEGRETOL	Carbamazepine	100 mg	Tablet, Chewable; Oral	Novartis.
NDA 018303	LOPRESSOR HCT	Hydrochlorothiazide; Metoprolol Tartrate.	25mg; 100mg	Tablet; Oral	Validus Pharms.
NDA 018878	INDOCIN	Indomethacin Sodium	EQ 1 mg Base/Vial	Injectable; Injection	Recordati Rare Diseases.
NDA 019404	OCUFEN	Flurbiprofen Sodium	0.03%	Solution/Drops; Ophthalmic	Allergan.
NDA 019661	CYTOVENE	Ganciclovir Sodium	EQ 500 mg Base/Vial	Injectable; Injection	Cheplapharm.
NDA 019697	ORTHO TRI–CYCLEN	Ethinyl Estradiol; Norgestimate.	0.035 mg, 0.035 mg, 0.035 mg; 0.18 mg, 0.215 mg, 0.25 mg.	Tablet; Oral	Janssen Pharms.
NDA 019766	ZOCOR	Simvastatin	80 mg	Tablet; Oral	Organon.
NDA 019814	BETAGAN	Levobunolol Hydrochloride	0.25%	Solution/Drops; Ophthalmic	Allergan.
NDA 019856	SINEMET CR	Carbidopa; Levodopa	25 mg, 100 mg; 50 mg, 200 mg.	Tablet, Extended Release; Oral.	Organon.
NDA 019907	OPTIPRANOLOL	Metipranolol Hydrochloride	0.3%	Solution/Drops; Ophthalmic	Bausch and Lomb.
NDA 019968	ULTRAVATE	Halobetasol Propionate	0.05%	Ointment; Topical	Sun Pharm Inds. Inc.
NDA 020010	LOTRISONE	Betamethasone Dipropionate; Clotrimazole.	EQ 0.05% Base; 1%	Lotion; Topical	Merck Sharp Dohme.
NDA 020381	NIASPAN	Niacin	500 mg; 750 mg; 1g	Tablet, Extended Release; Oral.	AbbVie Inc.
NDA 020412	ZERIT	Stavudine	15 mg; 20 mg; 30 mg; 40 mg.	Capsule; Oral	Bristol Myers Squibb.
NDA 020509	GEMZAR	Gemcitabine Hydrochloride	EQ 200 mg Base/Vial; 1 Gram (g) Base/Vial.	Injectable; Injection	Lilly.
NDA 020593	DEPACON	Valproate Sodium	100 mg Base/Milliliter (mL)	Injectable; Injection	AbbVie Inc.
NDA 020615	DURACLON	Clonidine Hydrochloride	5 mg/10 mL (0.5 mg/mL)	Injectable; Injection	Mylan Institutional.
NDA 020718	INTEGRILIN	Eptifibatide	2 mg/mL; 75 mg/100 mL	Injectable; Injection	Merck Sharp Dohme.
NDA 021005	SOLARAZE	Diclofenac Sodium	3%	Gel; Topical	Fougera Pharms.
NDA 021085	AVELOX	Moxifloxacin Hydrochloride	EQ 400 mg Base	Tablet; Oral	Bayer Healthcare.
NDA 021183	VIDEX EC	Didanosine	125 mg; 200 mg; 250 mg; 400 mg.	Capsule, Delayed Release Pellets; Oral.	Bristol Myers Squibb.
NDA 021241	ORTHO TRI–CYCLEN LO	Ethinyl Estradiol; Norgestimate.	0.025 mg, 0.025 mg, 0.025 mg; 0.18 mg, 0.215 mg, 0.25 mg.	Tablet; Oral-28	Janssen Pharms.
NDA 021300	CLARINEX	Desloratadine	0.5 mg/mL	Solution; Oral	Merck Sharp Dohme.
NDA 021312	CLARINEX	Desloratadine	2.5 mg; 5 mg	Tablet, Orally Disintegrating; Oral.	Organon.
NDA 021372	ALOXI	Palonosetron Hydrochloride.	EQ 0.25 mg Base/5 mL (EQ 0.05 mg Base/mL); EQ 0.075 mg Base/1.5 mL (EQ 0.05 mg Base/mL).	Injectable; Intravenous	Helsinn Healthcare.
NDA 021444	RISPERDAL	Risperidone	0.5 mg; 1 mg; 2 mg; 3 mg; 4 mg.	Tablet, Orally Disintegrating; Oral.	Janssen Pharms.
NDA 021455	BONIVA	Ibandronate Sodium	EQ 150 mg Base	Tablet; Oral	Hoffmann La Roche.
NDA 021605	CLARINEX D 24 HOUR	Desloratadine; Pseudoephedrine Sulfate.	5 mg; 240 mg	Tablet, Extended Release; Oral.	Organon.
NDA 021858	BONIVA	Ibandronate Sodium	EQ 3 mg Base/3 mL	Injectable; Intravenous	Hoffmann La Roche.
NDA 021860	SARAFEM	Fluoxetine Hydrochloride	EQ 10 mg Base; EQ 20 mg Base.	Tablet; Oral	Allergan.
NDA 021956	DUTOPROL	Hydrochlorothiazide; Metoprolol Succinate.	12.5 mg; EQ 25 mg Tartrate; 12.5 mg: EQ 50 mg Tartrate; 12.5 mg; EQ 100 mg Tartrate.	Tablet, Extended Release; Oral.	Concordia.
NDA 022064	XYZAL	Levocetirizine Dihydrochloride.	5 mg	Tablet; Oral	Chattem Sanofi.
NDA 022106	DORIBAX	Doripenem	250 mg/Vial; 500 mg/Vial	Injectable; Intravenous Infusion.	Shionogi, Inc.
NDA 022129	ULESFIA	Benzyl Alcohol	5%	Lotion; Topical	Shionogi, Inc.
NDA 022157	XYZAL	Levocetirizine Dihydrochloride.	2.5 mg/5 mL	Solution; Oral	Chattem Sanofi.
NDA 022321	EMBEDA	Morphine Sulfate; Naltrexone Hydrochloride.	20 mg, 0.8 mg; 30 mg, 1.2 mg; 50 mg, 2 mg; 60 mg, 2.4 mg; 80 mg, 3.2 mg; 100 mg, 4 mg.	Capsule, Extended Release; Oral.	Alpharma Pharms.
NDA 050261	DECLOMYCIN	Demeclocycline Hydrochloride.	75 mg; 150 mg; 300 mg	Tablet; Oral	Corepharma.
NDA 050405	KEFLEX	Cephalexin	EQ 250 mg Base; EQ 500 mg Base; EQ 750 mg Base.	Capsule; Oral	Pragma.
NDA 050529	PEDIAZOLE	Erythromycin Ethylsuccinate; Sulfisoxazole Acetyl.	EQ 200 mg Base/5 mL; EQ 600 mg Base/5 mL.	Granule; Oral	Ross Labs.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
ANDA 083082	CHLOROQUINE PHOSPHATE.	Chloroquine Phosphate	250 mg; 500 mg	Tablet; Oral	Hikma Pharms.
NDA 204592	ZORVOLEX	Diclofenac	18 mg	Capsule; Oral	Zyla.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17056 Filed 8–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2475]

Advisory Committee; Allergenic Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Allergenic Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Allergenic Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the July 9, 2024, expiration date.

DATES: Authority for the Allergenic Products Advisory Committee will expire on July 9, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sussan Paydar, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 71, Rm. 1333A, Silver Spring, MD 20993–0002, 301–796–4897, *Sussan.Paydar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Allergenic Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/allergenic-products-advisory-committee/charter-allergenic-products-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17052 Filed 8–8–22; 8:45 am]

BILLING CODE 4164–01–P