DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2032]

Determination That BUTISOL SODIUM (Butabarbital Sodium) Oral Tablets, 15 Milligrams, 50 Milligrams, and 100 Milligrams, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 if 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: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 000793	BUTISOL SODIUM	Butabarbital Sodium	15 mg; 50 mg; 100 mg	Tablet; Oral	Mylan Specialty, L.P.
NDA 007392	SECONAL SODIUM	Secobarbital Sodium	50 mg/Milliliter (mL)	Injectable; Injection	Eli Lilly and Co.
NDA 012665	VELBAN	Vinblastine Sulfate	10 mg/Vial	Injectable; Injection	Eli Lilly and Co.
NDA 017015	PAVULON	Pancuronium Bromide.	1 mg/mL; 2 mg/mL	Injectable; Injection	Schering-Plough Corp.
NDA 017919	ORTHO–NOVUM 1/35–28.	Ethinyl Estradiol; Norethindrone.	0.035 mg;1 mg	Tablet; Oral-28	Janssen Pharmaceuticals, Inc.
NDA 018554	EULEXIN	Flutamide	125 mg	Capsule; Oral	Schering-Plough Corp.
NDA 019151	RYTHMOL	Propafenone Hydrochloride.	150 mg, 225 mg, 300 mg	Tablet; Oral	GlaxoSmithKline.
NDA 019579	TERAZOL 7	Terconazole	0.4%	Cream; Vaginal	Janssen Pharmaceuticals, Inc.
NDA 019599	NAFTIN	Naftifine Hydrochloride.	1%	Cream; Topical	Sebela Ireland Limited.
NDA 019653	ORTHO CYCLEN–28	Ethinyl Estradiol; Norgestimate.	0.035 mg; 0.25 mg	Tablet; Oral-28	Janssen Pharmaceuticals, Inc.
NDA 019716	DIPROLENE	Betamethasone Dipropionate.	EQ 0.05% Base	Lotion, Augmented; Topical.	Merck Sharp & Dohme Corp.
NDA 019964	TERAZOL 3	Terconazole	0.8%	Cream; Vaginal	Janssen Pharmaceuticals, Inc.
NDA 020313	MIACALCIN	Calcitonin Salmon	200 International Units/Spray.	Metered Spray; Nasal	Mylan Ireland Limited.
NDA 020388	NAVELBINE	Vinorelbine Tartrate	EQ 10 mg Base/mL	Injectable; Injection	Pierre Fabre Medicament.
NDA 020413	ZERIT	Stavudine	1 mg/mL	For Solution; Oral	Bristol-Myers Squibb.
NDA 020741	PRANDIN	Repaglinide	0.5 mg; 1 mg; 2 mg	Tablet; Oral	Gemini Laboratories, LLC.
NDA 020872	CHILDREN'S ALLEGRA ALLERGY.	Fexofenadine Hydrochloride.	30 mg	Tablet; Oral	Sanofi-Aventis U.S., LLC.
NDA 021071	AVANDIA	Rosiglitazone Maleate.	EQ 8 mg Base	Tablets; Oral	SB Pharmco Puerto Rico, Inc.
NDA 021235	PROZAC WEEKLY	Fluoxetine Hydrochloride.	EQ 90 mg/Base	Delayed-Release Capsules; Oral.	Eli Lilly and Co.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021909	CHILDREN'S ALLEGRA HIVES.	Fexofenadine Hydrochloride.	30 mg	Tablet, Orally Disintegrating; Oral.	Sanofi-Aventis U.S., LLC.
NDA 022246	METOZOLV ODT	Metoclopramide Hydrochloride.	EQ 5 mg Base	Tablet, Orally Disintegrating; Oral.	Bausch Health US, LLC.
NDA 022291	PROMACTA	Eltrombopag Olamine	EQ 100 mg Acid	Tablet; Oral	Novartis.
NDA 022362	WELCHOL	Colesevelam Hydrochloride.	1.875 g/Packet	For Suspension; Oral	Daiichi Sankyo.
NDA 022396	DYLOJECT	Diclofenac Sodium	37.5 mg/mL (37.5 mg/mL)	Solution; Intravenous	Javelin Pharmaceuticals, Inc.
NDA 050368	ILOTYCIN	Erythromycin	0.5%	Ointment; Ophthalmic	Eli Lilly and Co.
NDA 050587	PRIMAXIN	Cilastatin Sodium; Imipenem.	EQ 250 mg Base/Vial; 250 mg/Vial.	Powder; Intravenous	Merck & Co., Inc.
NDA 201373	CHILDREN'S ALLEGRA HIVES.	Fexofenadine Hydrochloride.	30 mg/5 mL	Suspension; Oral	Sanofi-Aventis U.S., LLC.
NDA 208411	NARCAN	Naloxone Hydrochloride.	2 mg/Spray	Spray, Metered; Nasal.	Adapt Pharma.

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 NDAs and ANDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. 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: October 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' Forms FDA 3988, Transmittal of PMR/PMC Submissions for Drugs and Biologics, and FDA 3989, PMR/PMC Annual Status Report for Drugs and Biologics, are intended to facilitate submissions by drug and biological product application holders of complete and accurate information on postmarketing requirements (PMRs) and postmarketing commitments (PMCs) in a consistent format. Forms FDA 3988 and 3989 are published in draft form in Appendix A and B of the draft guidance for comment and are not intended to be used until the forms are finalized. The forms were developed, in part, in response to the recommendations from the Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) regarding the need for comparable information across annual status reports (ASRs) on PMRs and PMCs, to eliminate manual data entry, and to enhance FDA's ability to track PMRs and PMCs. These forms are expected to result in improved accuracy and timeliness of FDA's identification and review of those submissions containing information on PMRs and PMCs. This draft guidance covers the purpose of each form, when to use these forms, and how to submit these forms. The draft guidance also explains where applicants will be able to find the forms and instructions for their completion once the forms and instructions are finalized.

DATES: Submit either electronic or written comments on the draft guidance by December 21, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the collection of information set forth in this document by December 21, 2020.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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