has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. FDA, Guidance for Industry, ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' January 2017 (available at *https://www.fda.gov/media/94402/download*).
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Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06060 Filed 3–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0279]

Determination That Folic Acid, Oral Tablets, 1 Milligram, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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: 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 006135	Folic Acid	Folic Acid	1 milligram (mg)	Tablet; Oral	Eli Lilly & Co.
NDA 016131	CLOMID	Clomiphene Citrate	50 mg	Tablet; Oral	Sanofi-Aventis U.S. LLC.
NDA 016419	Propranolol Hydrochloride.	Propanolol Hydrochloride.	1 mg/milliliter (mL)	Injectable; Injection	Baxter Healthcare Corp.
NDA 017473	ORAP	Pimozide	1 mg; 2 mg	Tablet; Oral	Teva Pharms., USA, Inc.
NDA 019916	Morphine Sulfate	Morphine Sulfate	1 mg/mL; 5 mg/mL	Injectable; Injection	ICU Medical, Inc.
NDA 019967	ULTRAVATE	Halobetasol Propionate	0.05%	Cream; Topical	Sun Pharmaceutical Industries, Inc.
NDA 020647	ELDEPRYL	Selegiline Hydrochloride.	5 mg	Capsule; Oral	Somerset Pharms., Inc.
NDA 020925	TAVIST–1	Clemastine Fumarate	1.34 mg	Tablet; Oral	GlaxoSmithKline Consumer Healthcare.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021015 ...	ANDROGEL	Testosterone	12.5 mg/1.25 g Actuation.	Gel, Metered; Transdermal.	AbbVie Inc.
NDA 021204 ...	STARLIX	Nateglinide	60 mg; 120 mg	Tablets; Oral	Novartis Pharms., Corp.
NDA 021217 ...	EXALGO	Hydromorphone Hydrochloride.	8 mg; 12 mg; 16 mg; 32 mg.	Tablet, Extended-Release; Oral.	Specgx, LLC.
NDA 021365 ...	LEXAPRO	Escitalopram Oxalate ..	Equal to (EQ) 5 mg Base/5 mL.	Solution; Oral	Allergan Sales, LLC.
NDA 021490 ...	FEMCON FE	Ethinyl Estradiol; Norethindrone.	0.035 mg; 0.4 mg	Tablet, Chewable; Oral	Allergan Pharms., International, Ltd.
NDA 021860 ...	SARAFEM	Fluoxetine Hydrochloride.	EQ 15 mg Base	Tablet; Oral	Allergan Pharms. International, Ltd.
NDA 021870 ...	Fludeoxyglucose F–18	Fludeoxyglucose F–18	20–200 Millicurie/mL ...	Injectable; Intravenous	Feinstein Institute Medical Research.
NDA 022442 ...	REZIRA	Hydrocodone Bitartrate; Pseudoephedrine Hydrochloride.	5 mg/5 mL; 60 mg/5 mL.	Solution; Oral	Persion Pharms., LLC.
NDA 050757 ...	PREVPAC	Amoxicillin; Clarithromycin; Lansoprazole.	500 mg; 500 mg; 30 mg.	Capsule, Tablet, Capsule; Oral.	Takeda Pharms. USA, Inc.
NDA 203195 ...	SUPRAX	Cefixime	400 mg	Capsule; Oral	Lupin, Ltd.
NDA 207931 ...	TECHNIVIE	Ombitasvir; Paritaprevir; Ritonavir.	12.5 mg; 75 mg; 50 mg	Tablet; Oral	AbbVie Inc.
NDA 208624 ...	VIEKIRA XR	Dasabuvir Sodium; Ombitasvir; Paritaprevir; Ritonavir.	EQ 200 mg Base; 8.33 mg; 50 mg; 33.33 mg.	Tablet, Extended Release; Oral.	AbbVie Inc.

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 listed are unaffected by the discontinued marketing of the products subject to those NDAs. 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: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06059 Filed 3–23–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6644]

Fiscal Year 2021 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''FY 2021 Generic Drug Science and Research Initiatives Workshop.'' The purpose of the public workshop is to provide an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2017 (GDUFA II) to develop an annual list of science and research initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its Fiscal Year (FY) 2022 GDUFA science and research initiatives.

DATES: The public workshop will be held on June 23, 2021, from 8:30 a.m. to 4:30 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by July 23, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 23, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 23, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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