''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sam Raney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4732, Silver Spring, MD 20993, 240–402–7967, *Sameersingh.Raney@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240–402–7957, *Robert.Lionberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112–144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA I commitment letter) to work with industry and interested stakeholders on identifying science and research initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA was reauthorized until September 2022 through the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Pub. L. 115–52), and in September 2022, GDUFA was reauthorized until September 2027 through the Generic Drug User Fee Amendments of 2022 (GDUFA III) (Pub. L. 117–180, 136 Stat. 2155). In the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III commitment letter),[1] FDA agreed to conduct annual public workshops ''to solicit input from industry and stakeholders for inclusion in an annual list of GDUFA III regulatory science initiatives.'' This public workshop scheduled for May 11, 2023, and May 12, 2023, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to obtain input from industry and other interested stakeholders on identifying generic drug science and research initiatives for FY 2024. FDA is interested in receiving input about regulatory science initiatives for the ongoing years of the GDUFA III science and research program, and particularly for FY 2024.

Topics discussed during the workshop will likely include challenges and considerations for oral, parenteral, and other generic products, including complex products. Specific presentations and discussions at this workshop will be announced at a later date and may differ from the topics above. However, input about the topics above will help the Agency identify and expand its scientific focus for the next fiscal year.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2024 science and research initiatives. Information concerning the science and research initiatives for generic drugs can be found on the Science & Research website at *https://www.fda.gov/drugs/generic-drugs/science-research.*

III. Participating in the Public Workshop

Registration: Registration is free. Persons interested in attending this public workshop must register online at *https://fda.zoomgov.com/webinar/register/WN_J3MsCbCWQwyuA1AojKF_8Q.* Registration may be performed at any time before or during the workshop.

Requests for Oral Presentations: During online registration you may indicate if you wish to present your public comments. Requests to provide public comments via a pre-recorded presentation or a live presentation, including in-person or virtual presentations, should be submitted by 11:59 p.m. Eastern Time at the end of March 31, 2023. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the workshop. Based upon the public comment presentation requests received by March 31, 2023, at 11:59 p.m. Eastern Time, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin; we will select and notify participants by April 11, 2023. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than May 1, 2023, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. Please register online (as described above) to attend the workshop remotely (virtually). Registrants will receive a hyperlink that provides access to the webcast on both days.

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

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov* or on the Science & Research FDA website accessible at *https://www.fda.gov/drugs/generic-drugs/science-research.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02453 Filed 2–3–23; 8:45 am]

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[1] The GDUFA III commitment letter is available at *https://www.fda.gov/media/153631/download.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0218]

Determination That TRIAMCINOLONE ACETONIDE (Triamcinolone Acetonide) Topical Cream, 0.025% and 0.1%, 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 011601 ...	TRIAMCINOLONE ACETONIDE.	Triamcinolone Acetonide.	0.025%; 0.1%	Cream; Topical	Mylan.
NDA 012575 ...	ACTIFED W/CODEINE	Codeine Phosphate; Pseudoephedrine Hydrochloride; Triprolidine Hydrochloride.	10 Milligrams (mg)/5 Milliliters (mL); 30 mg5 mL; 1.25 mg/5 mL.	Syrup; Oral	GlaxoSmithKline.
NDA 016267 ...	DESFERAL	Deferoxamine Mesylate	2 Grams (g)/Vial	Injectable; Injection	Novartis.
NDA 017922 ...	DDAVP (NEEDS NO REFRIGERATION).	Desmopressin Acetate	0.01 mg/Spray	Spray, Metered; Nasal	Ferring Pharms., Inc.
NDA 018279 ...	K–TAB	Potassium Chloride	8 Milliequivalents	Tablet, Extended Release; Oral.	Abbvie.
NDA 018830 ...	TAMBOCOR	Flecainide Acetate	200 mg	Tablet; Oral	Alvogen.
NDA 018983 ...	COLYTE	Polyethylene Glycol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate Anhydrous.	227.1 g/Packet, 2.82 g/Packet, 6.36 g/Packet, 5.53 g/Packet, 21.5 g/Packet; 120 g/Packet, 1.49 g/Packet, 3.36 g/Packet, 2.92g/Packet, 11.36g/Packet; 360 g/Packet, 4.47 g/Packet, 10.08 g/Packet, 8.76 g/Packet, 34.08 g/Packet; 240 g/Bottle, 2.98 g/Bottle, 6.72g/Bottle, 5.84 g/Bottle, 22.72 g/Bottle; 227.1 g/Bottle, 2.82 g/Bottle, 6.36g/Bottle, 5.53 g/Bottle, 21.5g/Bottle;. 227.1 g/Bottle, 2.82 g/Bottle, 6.36 g/Bottle, 5.53 g/Bottle, 21.5 g/Bottle; 240 g/Bottle, 2.98 g/Bottle, 6.72 g/Bottle, 5.84 g/Bottle, 22.72 g/Bottle.	For Solution; Oral	Mylan Specialty, L.P.
NDA 019641 ...	TERAZOL 3	Terconazole	80 mg	Suppository; Vaginal ...	Janssen Pharms.
NDA 019821 ...	SORIATANE	Acitretin	10 mg; 17.5 mg; 22.5 mg; 25 mg.	Capsule; Oral	Stiefel Labs, Inc.
NDA 019898 ...	PRAVACHOL	Pravastatin Sodium	20 mg; 40 mg; 80 mg	Tablet; Oral	Bristol Myers Squibb Co.
NDA 019963 ...	RENOVA	Tretinoin	0.05%	Cream; Topical	Valeant.
NDA 020103 ...	ZOFRAN	Ondansetron Hydrochloride.	Equivalent to (EQ) 4 mg Base; EQ 8 mg Base; EQ 24 mg Base.	Tablet; Oral	Novartis.
NDA 020114 ...	ASTELIN	Azelastine Hydrochloride.	0.137 mg/Spray	Spray, Metered; Nasal	Mylan Specialty.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 020130 ...	ESTROSTEP FE	Ethinyl Estradiol; Norethindrone Acetate.	0.02 mg, 0.03 mg, 0.035 mg; 1 mg, 1 mg, 1 mg.	Tablet; Oral-28	Apil.
NDA 020279 ...	DERMATOP E EMOLLIENT.	Prednicarbate	0.1%	Cream; Topical	Valeant Bermuda.
NDA 020408 ...	TRUSOPT	Dorzolamide Hydrochloride.	EQ 2% Base	Solution/Drops; Ophthalmic.	Merck.
NDA 020658 ...	REQUIP	Ropinirole Hydrochloride.	EQ 0.25 mg Base; EQ 0.5 mg Base; EQ 1; EQ 2 mg Base; EQ 3 mg Base; EQ 4 mg Base; EQ 5 mg Base.	Tablet; Oral	GlaxoSmithKline.
NDA 020667 ...	MIRAPEX	Pramipexole Dihydrochloride.	0.125 mg; 0.25 mg; 0.5 mg; 0.75 mg; 1 mg; 1.5 mg.	Tablet; Oral	Boehringer Ingelheim.
NDA 020793 ...	CAFCIT	Caffeine Citrate	EQ 30 mg Base/3 mL	Solution; Oral	Hikma.
NDA 021076 ...	ALEVE–D SINUS & COLD.	Naproxen Sodium; Pseudoephedrine Hydrochloride.	220 mg, 120 mg	Tablet, Extended Release; Oral.	Bayer.
NDA 021158 ...	FACTIVE	Gemifloxacin Mesylate	EQ 320 mg Base	Tablet; Oral	LG Chem. Ltd.
NDA 021513 ...	ENABLEX	Darifenacin Hydrobromide.	EQ 7.5 mg Base; EQ 15 mg Base.	Tablet, Extended Release; Oral.	Apil.
NDA 021611 ...	OPANA	Oxymorphone Hydrochloride.	5 mg; 10 mg	Tablet; Oral	Endo Pharms.
NDA 021842 ...	ACTOPLUS MET	Metformin Hydrochloride; Pioglitazone Hydrochloride.	500 mg; EQ 15 mg Base.	Tablet; Oral	Takeda Pharms. USA.
NDA 022203 ...	ASTEPRO	Azelastine Hydrochloride.	0.137 mg/Spray	Spray, Metered; Nasal	Mylan Specialty.
NDA 022434 ...	ARGATROBAN IN SODIUM CHLORIDE.	Argatroban	50 mg/50 mL	Injectable; Intravenous	Eagle Pharms.
NDA 050537 ...	CLEOCIN T	Clindamycin Phosphate	EQ 1% Base	Solution; Topical	Pfizer.
NDA 050580 ...	AZACTAM	Aztreonam	500 mg/Vial	Injectable; Injection	Bristol Myers Squibb.
NDA 204031 ...	XARTEMIS XR	Acetaminophen; Oxycodone Hydrochloride.	325 mg; 7.5 mg	Tablet, Extended Release; Oral.	Mallinckrodt, Inc.
NDA 209481 ...	VANCOMYCIN HYDROCHLORIDE.	Vancomycin Hydrochloride.	EQ 250 mg Base/Vial	Powder; Intravenous ...	Mylan Labs Ltd.
NDA 209905 ...	EVEKEO ODT	Amphetamine Sulfate ..	2.5 mg	Tablet, Orally Disintegrating; Oral.	Azurity.

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: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02442 Filed 2–3–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0043]

Understanding Priorities for the Development of Digital Health Technologies To Support Clinical Trials for Drug Development and Review; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Understanding Priorities for the Development of Digital Health Technologies To Support Clinical Trials for Drug Development and Review.'' Convened by the Duke-Robert J. Margolis, MD Center for Health Policy and supported by a cooperative agreement between FDA and Duke-Margolis, the purpose of the public workshop is to understand the priorities for the development of Digital Health Technologies (DHTs) to support clinical drug trials, including accessibility, diversity, and clinical outcome measures using DHTs. Additionally, this public workshop meets a Prescription Drug User Fee Amendments (PDUFA VII) commitment to convene the first of a series of public workshops by the end of the second quarter (Q2), fiscal year (FY) 2023.

DATES: The public workshop will be held virtually on March 28, 2023, and March 29, 2023, from 1 p.m. to 5 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom