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FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4164–01–P

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

Platform. The link for the public workshop will be sent to registrants upon registration.

FOR FURTHER INFORMATION CONTACT: Capt. Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993, 301–796–3161, *Dianne.Paraoan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII), included as part of the FDA User Fee Reauthorization Act of 2022, highlights the goals of facilitating timely access to safe, effective, and innovative new medicines for patients. The commitments in the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 document (available at: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027*) focus on activities to enhance the use of DHTs to support drug development and review, including working with the Digital Health Center of Excellence.

To meet a PDUFA VII commitment, FDA agreed to convene a series of five public workshops with key stakeholders including patients, biopharmaceutical companies, DHT companies, and academia to gather input into issues related to the use of DHTs in regulatory decision-making. The objective of this first workshop is to understand priorities for the development of DHTs to support clinical drug trials, including the potential for DHTs to increase clinical trial accessibility and diversity, as well as the use of DHTs to capture clinical outcome measures. The public workshop scheduled for March 28 and 29, 2023, fulfills the commitment to convene the first of a series of five public workshops by the end of Q2, FY 2023.

II. Topics for Discussion at the Public Workshop

At the public workshop, FDA plans to discuss with stakeholders priorities and challenges for the development of DHTs to support clinical drug trials, including, but not limited to:

- improving participant access, increasing diversity, and facilitating engagement through remote trial-related measurements;
- understanding patient and industry perspectives;
- understanding opportunities for remote data acquisition directly from trial participants; and
- using DHTs to capture clinical outcomes measures.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://duke.is/pzkwx.* Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Registration is free and people interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations, please contact *Margolisevents@duke.edu* no later than March 7, 2023. Please note, closed captioning will be available automatically.

Dated: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02479 Filed 2–3–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1978]

Determination of Regulatory Review Period for Purposes of Patent Extension; DOPTELET

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DOPTELET and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 7, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 7, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 7, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 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 identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–E–1978 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; DOPTELET.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be