provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Grace Carmouze-Cunningham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.*

Dated: August 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19059 Filed 9–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3549]

Merck Sharp & Dohme LLC, et al.; Withdrawal of Approval of 35 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 35 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of October 5, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 001546	Guanidine (guanidine hydrochloride (HCl)) Tablets, 125 milligrams (mg).	Merck Sharp & Dohme LLC, 126 East Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065.
NDA 010841	Peganone (ethotoin) Tablets, 250 mg and 500 mg	Recordati Rare Diseases Inc., 100 Corporate Dr., Lebanon, NJ 08833.
NDA 016801	Xylocaine Preservative Free (lidocaine HCl) Injection, 1%, 2%, 4%, 10%, and 20%.	Fresenius Kabi USA, LLC, 3 Corporate Dr., Lake Zurich, IL 60047.
NDA 016822	FreAmine 8.5% (amino acids) Injection, 8.5 grams (g)/100 milliliters (mL). FreAmine HBC 6.9% (amino acids) Injection, 6.9 g/100 mL. FreAmine II 8.5% (amino acids) Injection, 8.5 g/100 mL. FreAmine III 10% (amino acids) Injection, 10 g/100 mL. FreAmine III 8.5% (amino acids) Injection, 8.5 g/100 mL. FreAmine III 8.5% with electrolytes (amino acids, magnesium acetate, phosphoric acid, potassium acetate, potassium chloride, sodium acetate) Injection, 8.5%; 110mg/100mL; 230mg/100mL; 10mg/100mL; 440mg/100mL; 690mg/100mL. FreAmine III 3% with electrolytes (amino acids, magnesium acetate, phosphoric acid, potassium chloride, sodium acetate, sodium chloride) Injection, 3%; 54mg/100mL; 40mg/100mL; 150mg/100mL; 200mg/100mL; 120mg/100mL.	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 017407	Catapres (clonidine HCl) Tablets, 0.1 mg, 0.2 mg, and 0.3 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877.
NDA 017425	Proglycem (diazoxide) Capsules, 50 mg and 100 mg	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 017534	Fiorinal (aspirin, butalbital, caffeine) Capsules, 325 mg/50 mg/40 mg. Fiorinal (aspirin, butalbital, caffeine) Tablets, 325 mg/50 mg/40 mg.	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 018582	Procalamine (amino acids, calcium acetate, glycerin, magnesium acetate, phosphoric acid, potassium chloride, sodium acetate, sodium chloride) Injection, 3%; 26mg/100mL; 3g/100mL; 54mg/100mL; 41mg/100mL; 150mg/100mL; 200mg/100mL; 120mg/100mL.	B. Braun Medical Inc.
NDA 018676	HepatAmine 8% (amino acids) Injection, 8g/100mL	Do.
NDA 018878	Indocin (indomethacin sodium) Injection, equivalent to (EQ) 1 mg base/vial.	Recordati Rare Diseases Inc.

Application No.	Drug	Applicant
NDA 019099	Dopamine HCl and Dextrose 5% Injection, 80 mg/100 mL and 320 mg/100 mL. Dopamine HCl and Dextrose 5% in plastic container Injection, 40 mg/100 mL and 160 mg/100 mL.	B. Braun Medical Inc.
NDA 019111	Tussionex Pennkinetic (chlorpheniramine polistirex, hydrocodone polistirex) Extended-Release Suspension, EQ 8 mg maleate/5 mL; EQ 10 mg bitartrate/5 mL.	UCB Inc., 1950 Lake Park Dr., Building 2100, Smyrna, GA 30080.
NDA 019429	Fiorinal with Codeine (aspirin, butalbital, caffeine, codeine phosphate) Capsules, 325 mg/50 mg/40 mg/30 mg.	AbbVie Inc.
NDA 019898	Pravachol (pravastatin sodium) Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
NDA 020281	Ultram (tramadol HCl) Tablets, 50 mg and 100 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 020381	Niaspan (niacin) Extended-Release Tablets, 375 mg, 500 mg, 750 mg, and 1 g. Niaspan Titration Starter Pack (niacin) Extended-Release Tablets, 375 mg, 500 mg, and 750 mg.	AbbVie Inc.
NDA 020544	Jadelle (levonorgestrel) Implants for Subdermal Use, 75 mg/implant.	Population Council, 1230 York Ave., New York, NY 10065.
NDA 020616	Kadian (morphine sulfate) Extended-Release Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, and 200 mg.	AbbVie Inc.
NDA 020636	Viramune (nevirapine) Tablets, 200 mg	Boehringer Ingelheim Pharmaceuticals, Inc.
NDA 021065	Femhrt (ethinyl estradiol, norethindrone acetate) Tablets, 0.0025 mg/0.5 mg and 0.005 mg/1 mg.	Allergan Pharmaceuticals International Limited c/o AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 021066	Zaditor (ketotifen fumarate) Ophthalmic Solution, EQ 0.025% base.	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134.
NDA 021123	Ultracet (acetaminophen, tramadol HCl) Tablets, 325 mg/37.5 mg.	Janssen Pharmaceuticals, Inc.
NDA 021513	Enablex (darifenacin hydrobromide) Extended-Release Tablets, EQ 7.5 mg base and EQ 15 mg base.	AbbVie Inc.
NDA 021615	Razadyne ER (galantamine hydrobromide) Extended-Release Capsules, EQ 8 mg base, EQ 16 mg base, and EQ 24 mg base.	Janssen Research and Development, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021790	Dacogen (decitabine) Injection, 50 mg/vial	Otsuka Pharmaceutical Co., Ltd., c/o Otsuka Pharmaceutical Development and Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850.
NDA 021830	Asacol HD (mesalamine) Delayed-Release Tablets, 800 mg	AbbVie Inc.
NDA 021844	Desonate (desonide) Gel, 0.05%	LEO Pharma A/S, c/o LEO Pharma Inc., 7 Giralda Farms, Madison, NJ 07940.
NDA 022292	Aptivus (tipranavir) Oral Solution, 100 mg/mL	Boehringer Ingelheim Pharmaceuticals, Inc.
NDA 022439	Zutripro (chlorpheniramine maleate, hydrocodone bitartrate, pseudoephedrine HCl) Oral Solution, 4 mg/5 mL; 5 mg/5 mL; 60 mg/5 mL.	Persion Pharmaceuticals LLC, 10 North Park Place, Suite 201, Morristown, NJ 07960.
NDA 022442	Rezira (hydrocodone bitartrate, pseudoephedrine HCl) Oral Solution, 5 mg/5 mL; 60 mg/5 mL.	Do.
NDA 204307	Vituz (chlorpheniramine maleate, hydrocodone bitartrate) Oral Solution, 4 mg/5 mL; 5 mg/5 mL.	Do.
NDA 204768	Tivorbex (indomethacin) Capsules, 20 mg and 40 mg	Genus Lifesciences Inc., 514 North 12th St., Allentown, PA 18102.
NDA 206619	Viekira Pak (dasabuvir sodium; ombitasvir, paritaprevir, ritonavir) Tablets, EQ 250 mg base; 12.5 mg/75 mg/50 mg.	AbbVie Inc.
NDA 208374	Bivalirudin in 0.9% Sodium Chloride Intravenous Solution, 250 mg/50 mL and 500 mg/100 mL.	Baxter Healthcare Corp., 1 Baxter Pkwy., Deerfield, IL 60015.
NDA 210583	Anjeso (meloxicam) Intravenous Solution, 30 mg/mL	Baudax Bio, Inc., 490 Lapp Rd., Malvern, PA 19355.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 5, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without approved new drug applications violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on October 5, 2023 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19013 Filed 9–1–23; 8:45 am]

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