DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0473]

GE HealthCare, et al.; Withdrawal of Approval of 18 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 18 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 9, 2025.

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 table 1 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.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 011386	Hypaque (diatrizoate sodium) for solution, 100%. Hypaque (diatrizoate sodium) solution, 40%.	GE HealthCare, 251 Locke Dr., Marlborough, MA 01752.
NDA 017944	MPI DMSA Kidney Reagent (technetium Tc 99m succimer kit), injectable.	Do.
NDA 018045	Emcyt (estramustine phosphate sodium) capsule, equivalent to (EQ) 140 milligrams (mg) phosphate.	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 018141	Technetium Tc 99m MPI MDP (technetium Tc-99m medronate kit), injectable.	GE HealthCare.
NDA 019697	Ortho Tri-Cyclen (ethinyl estradiol and norgestimate, 0.035 mg/0.180 mg; ethinyl estradiol and norgestimate, 0.035 mg/0.215 mg; ethinyl estradiol and norgestimate, 0.035 mg/0.250 mg) tablets.	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 019862	Indiclor (indium In-111 chloride) injectable, 2 millicurie/0.2 milliliters (mL).	GE HealthCare.
NDA 019937	Adenocard (adenosine) injectable, 3 mg/mL	Astellas Pharma US, Inc., 1 Astellas Way, Northbrook, IL 60062.
NDA 020357	Glucophage (metformin hydrochloride (HCl)) tablets, 500 mg, 625 mg, 750 mg, 850 mg, and 1 g.	EMD Serono, Inc., 200 Pier 4 Blvd., Suite 300, Boston, MA 02210.
NDA 020489	Androderm (testosterone) extended-release transdermal film, 1 mg/24 hours (h), 2.5 mg/24 h, 4 mg/24 h, and 5 mg/24 h.	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 020613	Alphagan (brimonidine tartrate) solution/drops, 0.2%	Allergan, Inc., 2525 Dupont Dr., Irvine, CA 92612.
NDA 021145	Vaniqa (eflornithine HCl) cream, 13.9%	AbbVie Inc.
NDA 021202	Glucophage XR (metformin HCl), extended-release tablets, 500 mg and 750 mg.	EMD Serono, Inc.
NDA 021565	Elestat (epinastine HCl) ophthalmic solution/drops, 0.05%	Allergan, Inc.
NDA 021756	Macugen (pegaptanib sodium) intravitreal injectable, EQ 0.3 mg acid/0.09 mL.	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 201152	Viramune XR (nevirapine) extended-release tablets, 100 mg and 400 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, P.O. Box 368, Ridgefield, CT 06877.
NDA 203585	Synribo (omacetaxine mepesuccinate) powder for subcutaneous injection, 3.5 mg/vial.	Teva Pharmaceuticals GmbH, C/O Teva Branded Pharmaceuticals Products R&D, 145 Brandywine Parkway, West Chester, PA 19380.
NDA 208424	GoNitro (nitroglycerin) sublingual powder, 0.4 mg/packet	G. Pohl-Boskamp GmbH & Co. KG, C/O Allegis Pharmaceuticals, LLC, 276 Nissan Parkway F100, Canton, MS 39046.
NDA 212121	Potassium Phosphates (potassium phosphate, dibasic and potassium phosphate, monobasic) solution, 4.5 g/15 mL (300 mg/mL), and 2.65 g/15 mL (175 mg/mL).	CMP Development LLC, 8026 East Marlboro Rd., Farmville, NC 27828.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of May 9, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA 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 table 1 that are in inventory on May 9, 2025 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: March 31, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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