4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1181]

Air Products and Chemicals, Inc.; Withdrawal of Approval of a New Drug Application and New Animal Drug Application for Helium, USP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) 205864 and the new animal drug application (NADA) 141-395 for the designated medical gas Helium, USP held by Air Products and Chemicals, Inc., 1940 Air Products Blvd., Allentown, PA 18106-5500 (Air Products). Air Products notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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; or Scott Fontana (HFV-180), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0656, Scott.Fontana@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Air Products has informed FDA that it is no longer marketing the designated medical gas Helium, USP and has requested that FDA withdraw approval of NDA 205864 and NADA 141-395 under the processes in § 314.150(c) (21 CFR 314.150(c)) and § 514.115(d) (21 CFR 514.115(d)). Air Products has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated

application under § 314.150(c) or an NADA or abbreviated new animal drug application under § 514.115(d) is without prejudice to refiling.

Therefore, approval of NDA 205864 and NADA 141-395, and all amendments and supplements thereto, are hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Introduction or delivery for introduction into interstate commerce of Helium, USP, without an approved new drug application or an approved new animal drug application violates sections 505(a), 512(a), 301(a), and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), 360b(a)(1), 331(a), and 331(d)). Any Helium, USP manufactured by Air Products pursuant to these applications that is in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug product has reached its expiration date or otherwise become violative, whichever occurs first.

Dated: March 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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