regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, EXXUA (gepirone hydrochloride) indicated for treatment of major depressive disorder in adults. Subsequent to this approval, the USPTO received a patent term restoration application for EXXUA (U.S. Patent No. 7,538,116) from Fabre-Kramer Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated February 6, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of EXXUA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for EXXUA is 14,390 days. Of this time, 6,226 days occurred during the testing phase of the regulatory review period, while 8,164 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* May 2, 1984. Fabre-Kramer Pharmaceuticals, Inc. claims that October 1, 1989, is the date the investigational new drug application (IND) became effective. However, FDA's records indicate that the effective date of an earlier IND was May 2, 1984, which was 30 days after FDA received the earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 18, 2001. The applicant claims July 19, 1999, as the date the new drug application (NDA) for EXXUA (NDA 21164) was initially submitted. However, FDA records indicate that NDA 21164, submitted on October 1, 1999, was incomplete. FDA refused the application and notified the applicant of this fact by letter dated November 30, 1999. The complete NDA was then submitted on May 18, 2001, which is considered to be the initially submitted date.

3. *The date the application was approved:* September 22, 2023 5:47:00 p.m. FDA has verified the applicant's claim that NDA 21164 was approved on September 22, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 10, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24109 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4560]

Linde, 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) 205851 and the new animal drug application (NADA) 141–389 for the designated medical gas Helium, USP held by Linde, Inc., 175 East Park Dr., Tonawanda, NY 14150–7844. Linde, Inc. 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 November 18, 2024.

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: On March 12, 2024, Linde, Inc. informed FDA that it is no longer marketing the designated medical gas Helium, USP and requested that FDA withdraw approval of NDA 205851 and NADA 141–389 under the processes in § 314.150(c) (21 CFR 314.150(c)) and § 514.115(d) (21 CFR 514.115(d)). Linde, Inc. 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 205851 and NADA 141–389, and all amendments and supplements thereto,

are hereby withdrawn as of November 18, 2024. 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 Linde, Inc. pursuant to these applications that is in inventory on November 18, 2024 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: October 9, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24106 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2303]

Core Patient-Reported Outcomes in Cancer Clinical Trials; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' This final guidance provides recommendations to sponsors regarding the collection of a core set of patient-reported clinical outcomes (herein referred to as core patient-reported outcomes) in cancer clinical trials and related considerations for instrument selection and trial design. This final guidance focuses on patient-reported outcome (PRO) measures and is specific to registration trials for anti-cancer therapies intended to demonstrate an effect on survival, tumor response, or delay in the progression of a malignancy.

DATES: The announcement of the guidance is published in the **Federal Register** on October 18, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2020–D–2303 for ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Vishal Bhatnagar, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2113, Silver Spring, MD 20993–0002, 240–402–3696; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7910.

SUPPLEMENTARY INFORMATION: