GENERAL SERVICES ADMINISTRATION

[Notice–P–2024–15; Docket No. 2024–0002; Sequence No. 49]

Notice of Availability for the Record of Decision on the Final Environmental Impact Statement for the Alcan Land Port of Entry Expansion and Modernization in Alcan, Alaska

AGENCY: Public Buildings Service (PBS), U.S. General Services Administration (GSA).

ACTION: Notice of availability (NOA).

SUMMARY: GSA issued a Record of Decision (ROD) on the Final Environmental Impact Statement (EIS) for the Alcan Land Port of Entry Expansion and Modernization in Alcan, Alaska on October 18, 2024. The ROD was prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, the Council on Environmental Quality Regulations, and the GSA PBS NEPA Desk Guide.

DATES: *Applicable:* Friday, October 18, 2024.

ADDRESSES: The ROD may be found online at the following website: *www.gsa.gov/alcan.*

FOR FURTHER INFORMATION CONTACT: Aaron Evanson, Capital Project Manager, *AlcanLPOE@gsa.gov* or 206–445–5876.

SUPPLEMENTARY INFORMATION:

Background

The Alcan LPOE is located at Milepost 1221.8 on the Alaska Highway, 0.43 miles from the U.S./Canada Border. The existing Alcan LPOE is owned and managed by GSA and is operated by the U.S. Department of Homeland Security's Customs and Border Protection (CBP). The Alcan LPOE is the only 24-hour port serving privately-owned vehicles (POVs) and commercial traffic between the Yukon Territory, Canada, and mainland Alaska. GSA is the lead agency for the Final EIS and the Native Village of Northway is a cooperating agency.

GSA proposes to build an expanded and modernized LPOE and new housing units at Alcan, Alaska, to replace the existing facilities. The Final EIS describes the purpose and need for the proposed project, the alternatives considered, the existing environment that could be affected, the potential impacts resulting from each of the alternatives, and proposed best management practices and mitigation measures.

On April 7, 2023, GSA published a Notice of Intent for the EIS and underwent a 40-day scoping period. A Draft EIS was issued over a 45-day public comment period on February 26, 2024. Comments received, along with GSA's responses, during the Final EIS 30-day waiting period, which ended on October 7, 2024, are provided in Appendix A of the ROD.

Preferred Alternative

As noted in the ROD, GSA has chosen to implement Alternative 1: Expansion and Modernization in Place as defined in the Final EIS. This decision is based on the Final EIS issued in September 2024; associated technical reports; comments from federal and state agencies, stakeholders, members of the public, and elected officials; and other resources contained in the administrative record.

Alternative 1 consists of expanding and modernizing the Alcan LPOE and will include: site preparation and grading; construction of a new Main LPOE Building, enclosed inspection vehicle spaces, new housing units with improved security measures, an indoor firing range, and a helicopter landing zone; and demolition of the existing LPOE structures. GSA will need authorization for use of up to 6.5 acres extending into the Tetlin NWR for the proposed helicopter landing zone.

All facility and infrastructure improvements proposed under Alternative 1 will incorporate a sustainable, climate-resilient, cyber-secure, and operationally efficient design. GSA will seek to meet or exceed energy and sustainability goals established by federal guidelines and policies, along with industry standard building codes and best practices.

There will be approximately 15 acres of temporary ground disturbance and 5 acres of permanent ground disturbance under Alternative 1. Approximately 5 acres will be used as a staging area during construction. There are currently 8 acres of impermeable surfaces at the LPOE; expansion and modernization will add approximately 4 acres of impervious surfaces. Given the seasonal constraints of construction work in Alaska, Alternative 1 will likely follow a six-year implementation timeline, which will be phased to avoid disruption to LPOE operations.

GSA intends to implement and comply with all mitigation measures as detailed in the ROD.

Anamarie Crawley,

Director, R10 Facilities Management Division, Northwest/Arctic Region 10, U.S. General Services Administration.

[FR Doc. 2024–23879 Filed 10–17–24; 8:45 am]

BILLING CODE 6820–DL–P

GOVERNMENT PUBLISHING OFFICE

Depository Library Council Meeting

AGENCY: U.S. Government Publishing Office.

ACTION: Notice of meeting.

SUMMARY: The Depository Library Council (DLC) will meet virtually in conjunction with the Federal Depository Library Conference from Monday, October 21, 2024, through Wednesday, October 23, 2024. The meetings will take place online, and anyone may register to attend at *https://www.fdlp.gov/2024-fdl-conference.* Closed captioning will also be provided. The purpose is to discuss matters affecting the Federal Depository Library Program. All sessions are open to the public.

DATES: October 21–23, 2024.

Hugh Nathanial Halpern,

Director, U.S. Government Publishing Office.

[FR Doc. 2024–24114 Filed 10–17–24; 8:45 am]

BILLING CODE 1520–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3993]

Postoperative Nausea and Vomiting: Developing Drugs for Prevention; Draft 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 draft guidance for industry entitled ''Postoperative Nausea and Vomiting: Developing Drugs for Prevention.'' This guidance provides recommendations regarding the design of clinical trials for the prevention of postoperative nausea and vomiting in adults, including considerations for eligibility criteria, trial design features, efficacy evaluations, and safety assessments.

DATES: Submit either electronic or written comments on the draft guidance by December 17, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2024–D–3993 for ''Postoperative Nausea and Vomiting: Developing Drugs for Prevention.'' 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 the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Mary Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5350, Silver Spring, MD 20993–0002, 301–796–0260.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Postoperative Nausea and Vomiting: Developing Drugs for Prevention.'' Postoperative nausea and vomiting (PONV) is a serious, common, and distressing complication of surgery occurring within the 0- to 24-hour postoperative period in approximately 30 percent of the general surgical population and increasing to as high as 80 percent in high-risk cohorts. Nausea and vomiting following surgery can cause serious complications, including electrolyte imbalances and dehydration, can have a significant impact on how patients are functioning, and may prolong hospitalization and recovery from surgery. Additional complications of uncontrolled PONV can include esophageal tears, wound dehiscence, and decreased self-care and functional ability. Several risk factors have been associated with the development of PONV in adults. These include patient-specific risk factors (*e.g.,* female sex, a history of PONV and/or motion sickness, nonsmoking status, and young age) as well as intraoperative risk factors (*e.g.,* type of surgery and anesthesia administered) and postoperative risk factors (*e.g.,* opioid administration). Volatile anesthetic agents are the primary cause of early PONV within the 0- to 2-hour postoperative period.

Current treatment guidelines recommend that adults with at least one of the identified risk factors receive combination pharmacological PONV prophylaxis, which includes drugs from more than one pharmacological class that act on different receptor sites. Importantly, some antiemetics are commonly being administered off-label as part of the combination prophylaxis, as they have not been FDA-approved for this indication. Therefore, this draft guidance, when finalized, will help facilitate trials that can lead to FDA approval for a PONV prevention indication.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Postoperative Nausea and Vomiting: Developing Drugs for Prevention.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 relating to clinical trials associated with investigational new drug applications have been approved under OMB control

number 0910–0014. The collections of information in 21 CFR part 50 relating to protection of human subjects have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 9, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24107 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–E–0199]

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

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 EXXUA 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 December 17, 2024. 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 April 16, 2025. 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 December 17, 2024. 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–2024–E–0199 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EXXUA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to