

Mulligan, Project Manager, JCK Federal Building, 230 S. Dearborn, Suite 3600, Chicago, IL 60604

Comments sent by any other method or to any other address or individual may not be considered by GSA. Comments received or postmarked after the 30-day Final EIS Wait Period may not be considered by GSA. All comments received are part of the public record. All personal identifying information (*e.g.*, name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. GSA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT:

Joseph Mulligan, GSA Project Manager, 312-505-5426, at HartfordCourthouse@gsa.gov.

SUPPLEMENTARY INFORMATION: GSA has considered and incorporated stakeholder input and public comments provided during the scoping and Draft EIS comment periods to develop the Final EIS and determine the Preferred Alternative.

GSA's Preferred Alternative for the site acquisition, and subsequent design, construction and operation of a new federal courthouse in Hartford is Alternative 2, the Allyn Site. Under the Preferred Alternative, GSA would acquire the Allyn Site, consisting of approximately 2.19 acres of land located at 154 Allyn Street. The Allyn Site is bounded by Church Street to the north, High Street to the west, Allyn Street to the south, and mixed-use and religious buildings along its eastern perimeter. It is in the central business district of Hartford and is one block north of Bushnell Park. The Allyn Site currently serves as a surface parking lot. Under the Preferred Alternative, the new federal courthouse would likely contain up to two levels of underground secure parking. The majority of the Allyn Site, approximately 2 acres, would be excavated and graded in preparation for construction, and a small portion, approximately 0.25 acres, would be used as a staging area. GSA may lease a vacant paved lot in the vicinity of the Allyn Site for staging purposes due to the limited space availability at the site. The Project would generate approximately 50,000 to 75,000 cubic yards of excavated materials. A new landscape plan would be developed using native plantings. There appears to be adequate public parking in proximity to the Allyn Site, however, GSA may pursue options to provide additional parking such as entering into a lease with a commercial parking operator.

Background

The Court currently operates at three facilities: the Richard C. Lee U.S. Courthouse in New Haven (its headquarters location), the Brien McMahon Federal Building and U.S. Courthouse in Bridgeport, and the Abraham A. Ribicoff Federal Building and Courthouse in Hartford (Ribicoff Federal Building and Courthouse).

The Ribicoff Federal Building and Courthouse, constructed in 1963, does not have the capacity to accommodate the functions and operations of the Court. The facility is inadequate in size and configuration for the Court's existing operations, including deficiencies in judicial, juror, and detainee circulation and overall facility security. The Court's long-term facilities planning and GSA's feasibility studies concluded that relocating the Court's headquarters to Hartford would provide efficiencies in judicial operations across the State. The results from these studies led to GSA's proposal to locate the Court and related agencies at a new courthouse in Hartford.

GSA has prepared a Final EIS to assess the potential impacts of this project.

Alternatives Considered

GSA evaluated two action alternatives in the Final EIS. Both would involve site acquisition, design, construction, and operation of a new federal courthouse in Hartford: (1) Alternative 1, Woodland Site, located at 61 Woodland Street, and (2) Alternative 2, Allyn Site, located at 154 Allyn Street. Key features of the proposed courthouse include (a) total building gross square footage of up to 281,000; (b) eleven courtrooms and eighteen judges chambers; (c) offices for the Court and related agencies; and (d) sixty-six secure parking spaces. GSA also considered a No Action alternative. 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. The resource areas analyzed in the Final EIS include land use; utilities; traffic and transportation; air quality; solid and hazardous waste; socioeconomic; protection of children's health and safety; cultural resources; geology, topography, and soils; water resources; and visual resources. Based on the analysis presented in the Final EIS, impacts from the Preferred Alternative on all resource areas would

be less-than-significant (*i.e.*, negligible, minor, or moderate).

The Final EIS was prepared in compliance with the National Environmental Policy Act (NEPA) NEPA, as amended (42 United States Code [U.S.C.] *et seq.*), which requires federal agencies to examine the impacts of their proposed projects or actions on the human and natural environment and consider alternatives to the proposal before deciding on taking an action. The Final EIS complies with the GSA PBS NEPA Desk Guide and other relevant federal and state laws and regulations and executive orders.

Further information about the project can be viewed at: <http://gsa.gov/hartfordcourthouse>.

Jesse Lafreniere,

Director, Design and Construction Division, U.S. General Services Administration, PBS New England Region.

[FR Doc. 2025-08090 Filed 5-8-25; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

[Notice-P-2025-03; Docket No. 2025-0002; Sequence No. 3]

Notice of Availability for a Final Environmental Impact Statement (EIS) and Floodplain and Wetlands Assessment and Statement of Findings for the Grand Portage Land Port of Entry (LPOE) Modernization and Expansion Project in Grand Portage, Minnesota

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

ACTION: Notice of Availability (NOA); Public Notice of Floodplain and Wetlands Assessment and Statement of Findings.

SUMMARY: This notice announces the availability of the Final EIS, which examines potential environmental impacts from the modernization and expansion of the Grand Portage LPOE, located within the Grand Portage Reservation of the Grand Portage Band of Lake Superior Chippewa (herein referred to as the Grand Portage Band). The existing Grand Portage 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 Final EIS describes the purpose and need for the project; 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.

The Final EIS also includes a Floodplain and Wetlands Assessment and Statement of Findings as a result of potential construction in a floodplain and wetlands at the Grand Portage LPOE. Based on impacts analyses and public comments, GSA has identified the Proposed Action as described in the Final EIS as its preferred alternative.

DATES: The Final EIS Wait Period begins with publication of this NOA in the **Federal Register** and will last for 30 days until June 8, 2025. Any final written comments must be received or postmarked by the last day of the Wait Period (see the **ADDRESSES** section of this NOA on how to submit comments). After the Wait Period, GSA will issue the Record of Decision (ROD).

ADDRESSES: A copy of the Final EIS can be found on the GSA website at: <https://www.gsa.gov/about-us/gsa-regions/region-5-great-lakes/buildings-and-facilities/minnesota/grand-portage-land-port-of-entry>. Hard copies are also available at the following locations: Grand Portage Tribal Council Office, 83 Stevens Rd., Grand Portage, MN 55605; Grand Portage Community Center, 73 Upper Rd., Grand Portage, MN 55605; Grand Portage Trust Lands, 27 Store Rd., Grand Portage, MN 55605.

Public Comments

Members of the public may submit comments by any of the following methods. All comments will be considered equally and will be part of the public record.

- Electronic comments should be submitted to the email address listed below.

matthew.heiman@gsa.gov.

Please include 'Grand Portage LPOE Final EIS' in the subject line.

- Written comments should be mailed to: ATTN: Matthew Heiman, Senior Project Manager, Grand Portage LPOE Final EIS, U.S. General Services Administration, c/o Potomac-Hudson Engineering, Inc., 77 Upper Rock Circle, Suite 302, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Questions and comments on the Final EIS should be directed to: Matthew Heiman, Senior Project Manager, GSA at the following email address: *matthew.heiman@gsa.gov*.

SUPPLEMENTARY INFORMATION:

Wait Period

The views and comments of the public are necessary in helping GSA in its decision-making process. The public review process will be accomplished

through direct mail correspondence to appropriate federal, state, and local agencies, and to private organizations and citizens who have previously expressed, or are known to have, an interest in the project. The Final EIS has considered previous input provided during the scoping and Draft EIS comment periods.

Background

The existing 5.7-acre LPOE serves vehicles and pedestrians crossing the U.S.-Canada border between the Grand Portage Reservation in the U.S. and Neebing, Ontario in Canada. The Feasibility Study performed in 2019 determined that the existing structures do not contain the necessary square footage as specified by CBP's space and facility requirements (also referred to as Program of Requirements [POR]). In addition, the facility lacks outbound inspection capabilities. Following preparation of the Feasibility Study, a Program Development Study (PDS) was initiated as the next step in the design process to further refine potential alternatives under consideration. From the PDS process, viable alternatives were further refined into the Proposed Action analyzed within the Final EIS, in collaboration with the Grand Portage Band, who is serving as a Cooperating Agency for this EIS.

GSA has prepared this Final EIS for the purpose of analyzing the potential environmental, cultural, and economic impacts resulting from the Proposed Action to modernize and expand the existing Grand Portage LPOE.

Alternatives Under Consideration

The Proposed Action would consist of modernization and expansion of existing Grand Portage LPOE facilities as described in the PDS. Under the Proposed Action, GSA would replace the Grand Portage LPOE with a modernized facility on an expanded footprint, expanding the existing 5.7-acre operational footprint to a total operational footprint of approximately 10.4 acres. GSA would also upgrade the electrical distribution system leading to the LPOE by installing a 7.3-mile buried three-phase power line within Arrowhead Cooperative's existing utility right-of-way along the western side of Highway 61. GSA also considered the No Action Alternative, which assumes that GSA would not expand or modernize the Grand Portage LPOE or install the three-phase power line.

The purpose of the Proposed Action is for GSA to support CBP's mission by modernizing and expanding the Grand Portage LPOE. The existing LPOE does not meet CBP's current needs and does

not allow for expeditious and safe inspection of the traveling public. The deficiencies fall into two broad categories: deficiencies in the overall site layout and substandard building conditions. Therefore, to bring the Grand Portage LPOE operations in line with design standards and operational requirements, implementation of the Proposed Action is needed to (1) address space constraints and inefficient traffic flows; (2) shorten and expedite vehicle processing time, to include improving daily commutes across the U.S.-Canada border; (3) decrease congestion and long wait times during the peak travel season; (4) allow CBP to process a higher volume of vehicles traveling to and from Canada, to include further accommodation of potential future spikes in travelers crossing the U.S.-Canada border; and (5) provide a wider single lane for large semi-trucks hauling wind turbine components from Canada.

The Final EIS analyzes the potential impacts of the proposed alternatives on environmental resources including geology, water, biological resources, air quality, noise, traffic and transportation, land use and visual resources, infrastructure and utilities, socioeconomics, cultural resources, and human health and safety. The Final EIS concludes that impacts to all resource areas would be less-than-significant (*i.e.*, negligible, minor, or moderate). Impact reduction measures are presented in the Final EIS to reduce potential adverse effects.

GSA is currently conducting formal consultation with the Grand Portage Band Tribal Historic Preservation Officer (THPO) as required under Section 106 of the National Historic Preservation Act to determine impacts to historic properties. Mitigation measures may be determined in consultation between GSA, the THPO, and applicable consulting parties.

Under the Endangered Species Act (ESA), GSA coordinated with the U.S. Fish and Wildlife Service (USFWS) per Section 7 requirements to determine effects to federally protected species. GSA determined that there would be no adverse effects to federally threatened or endangered species with implementation of impact avoidance measures; USFWS concurred with these findings. GSA's findings and correspondence with USFWS are incorporated in the Final EIS.

The project area occurs within a region unmapped by the Federal Emergency Management Agency for floodplains and floodways. As information is currently unavailable that definitively indicates the presence or

location of floodplains relative to the project area, GSA has assumed that the project area is located within a 1-percent-annual-chance or 0.2-percent-annual-chance floodplain for purposes of complying with Executive Order 11988 and the GSA Floodplain Management Desk Guide, and until such time that a floodplain hazard study can be conducted. In addition, based on a wetland delineation conducted for the project, approximately 3.3 acres of wetlands occur within the project area. GSA prepared a Floodplain and Wetlands Assessment and Statement of Findings addressing potential impacts on floodplains and wetlands, which is included in the Final EIS. Final design of the Grand Portage LPOE would incorporate standard measures, including those specified in GSA Interim Core Building Standards as well as by the authority having jurisdiction, to reduce or manage stormwater flows as well as any potential impacts to the floodplain if present. GSA would coordinate as necessary with the Grand Portage Band to obtain appropriate permits and approvals related to wetlands disturbance under the Clean Water Act. Further, GSA would consider options to minimize, avoid, or mitigate potential impacts, as required by the U.S. Army Corps of Engineers and/or the Grand Portage Band.

Russell Riberto,
Regional Commissioner, Great Lakes Region 5, U.S. General Services Administration.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0679]

Determination That VOSOL (Acetic Acid, Glacial) 2% Otic Solution/Drops; and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route

of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS

Application No.	Drug name	Active ingredient(s)	Dosage form/route	Strength(s)	Applicant
NDA 012179	VOSOL	Acetic Acid, Glacial	2%	Solution/Drops; Otic	Hikma.
NDA 012836	PERSANTINE	Dipyridamole	25 Milligrams (mg); 50 mg; 75 mg.	Tablet; Oral	Boehringer Ingelheim.
NDA 013790	CORDRAN	Flurandrenolide	0.05%	Lotion; Topical	Almirall.
NDA 016758	NAVANE	Thiothixene Hydrochloride	Equivalent to (EQ) 5 mg Base/Milliliters (mL).	Concentrate; Oral	Pfizer.
NDA 017604	NALFON	Fenoprofen Calcium	EQ 200 mg Base; EQ 400 mg Base.	Capsule; Oral	Key Therapeutics.
NDA 019737	METROGEL	Metronidazole	0.75%	Gel; Topical	Galderma Laboratories LP.
NDA 019909	ZOVIRAX	Acyclovir	200 mg/5 mL	Suspension; Oral	Norvium Bioscience.
NDA 019922	CORLOPAM	Fenoldopam Mesylate	EQ 10 mg Base/mL	Injectable; Injection	Hospira.
NDA 020212	ZINECARD	Dexrazoxane Hydrochloride.	EQ 250 mg Base/Vial; EQ 500 mg Base/Vial.	Injectable; Injection	Pfizer.
NDA 020605	ZOFRAN	Ondansetron Hydrochloride.	EQ 4 mg Base/5 mL	Solution; Oral	Sandoz.
NDA 020636	VIRAMUNE	Nevirapine	200 mg	Tablet; Oral	Boehringer Ingelheim.
NDA 020645	AMMONUL	Sodium Benzoate; Sodium Phenylacetate.	10%; 10% (5 Grams (g)/50 mL; 5 g/50 mL).	Solution; Intravenous	Bausch Health.
NDA 020934	LUXIQ	Betamethasone Valerate	0.12%	Aerosol, Foam; Topical	Norvium Bioscience.