

2018 (Docket No. FDA-2018-P-2506), under 21 CFR 10.25 and 21 CFR 10.30, requesting that the Agency determine whether AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs that refer to this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-24604 Filed 11-8-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act, the National Institutes of Health (NIH) is issuing this notice to advise the public that an environmental impact statement will be prepared for the Surgery, Radiology and Lab Medicine Building with associated Utility Vault and Patient Parking Garage project located on the National Institutes of Health, Bethesda Campus, Bethesda, Maryland.

DATES: The Scoping Meeting is planned for November 28, 2018, from 6 p.m.-9 p.m., with the formal presentation to begin at 7 p.m. Scoping comments must be postmarked no later than December 29, 2018, to ensure they are considered.

ADDRESSES: The Scoping Meeting will be held at 6001 Executive Boulevard, Rockville, MD 20852. All comments and questions on the Scoping Meeting and the Environmental Impact Statement should be directed to Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301-496-7775; fax 301-480-0204; or email: nihnepa@mail.nih.gov.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301-496-7775; fax 301-480-0204; or email: nihnepa@mail.nih.gov. For the purpose of National Institutes of Health (NIH) and its National Environmental Policy Act (NEPA) procedures, the delegation of authority to administer, interpret and oversee the applicable environmental laws, Executive Orders and regulations for the NIH including the authority to oversee and manage the NIH NEPA program for assessing environmental impacts and publish final decisions has been given to the Director, Office of Research Facilities Development and Operation, Mr. Daniel G. Wheeland.

SUPPLEMENTARY INFORMATION: The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to

enhance health, lengthen life, and reduce illness and disability. In order to fulfill and uphold this mission the infrastructure of the NIH Bethesda Campus must be able to support the NIH's biomedical research programs.

The proposed Surgery, Radiology and Lab Medicine Building with associated Utility Vault and Patient Parking Garage project is to house General Radiology and Imaging Services (RADIS), the Department of Perioperative Medicine (DPM), the Department of Laboratory Medicine (DLM) and the relocated functions for the National Cancer Institute (NCI) in a state-of-the-art, safe, functionally efficient, flexible and cost-effective facility. During the study period, NIH expanded the building program to also include space for the National Heart, Lung & Blood Institute's (NHLBI) Cardiovascular Intervention Program (Cath Lab) and for the Interventional Radiology (IR) Program.

The proposed project consists of nine (9) levels above grade (including interstitial floors and a roof penthouse) and two (2) levels below grade. The proposed 505,200 building gross square feet (BGSF) of new construction will be linked to the west lab wing of the existing CRC (Building 10), which will include an additional 82,960 BGSF of interior renovation. The proposed new building addition foot print of 53,270 BGSF will be positioned between the CRC and Convent Drive.

The proposed project scope also includes the relocation of a portion of the existing campus utility tunnel, reconstruction of the displaced children's playground and connection to the new Pedestrian Tunnel that will be constructed with the proposed Patient Parking Garage across Convent Drive. Additionally, the project will include the installation of supporting infrastructure, such as emergency generators and medical gas storage, in the new Utility Vault and Utility Yard that will be constructed across Convent Drive as part of a separate, enabling project.

In accordance with 40 CFR 1500-1508 and Health and Human Services (HHS) environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed project. The EIS will evaluate the impacts of the alternatives should development occur as proposed. Among the items the EIS will examine are the implications of the project on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services.

To ensure that the public is afforded the greatest opportunity to participate in

the planning and environmental review process, NIH is inviting oral and written comments on the proposed project and related environmental issues.

The NIH will be sponsoring a public Scoping Meeting to provide individuals an opportunity to share their ideas, including recommended alternatives and environmental issues the EIS should consider. All interested parties are encouraged to attend. NIH has established a 30-day public comment period for the scoping process.

Dated: October 29, 2018.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.

[FR Doc. 2018-24557 Filed 11-8-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651-0096]

Agency Information Collection Activities: Transfer of Cargo to a Container Station

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted (no later than December 10, 2018) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to dhsdeskofficer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border

Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229-1177, Telephone number (202) 325-0056 or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (Volume 83 FR Page 33233) on July 17, 2018, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Transfer of Cargo to a Container Station.

OMB Number: 1651-0096.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: Before the filing of an entry of merchandise for the purpose of breaking bulk and redelivering cargo, containerized cargo may be moved from the place of unloading to a designated container station or may be received directly at the container station from a bonded carrier after transportation in-bond in accordance with 19 CFR 19.41. This also applies to loose cargo as part of containerized cargo. In accordance with 19 CFR 19.42, the container station operator may make a request for the transfer of a container to the station by submitting to CBP an abstract of the manifest for the transferred containers including the bill of lading number, marks, numbers, description of the contents and consignee.

Estimated Number of Respondents: 14,327.

Estimated Number of Annual Responses per Respondent: 25.

Estimated Total Annual Responses: 358,175.

Estimated Time per Response: 7 minutes.

Estimated Total Annual Burden Hours: 41,548.

Dated: November 6, 2018.

Seth D. Renkema,
Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.
[FR Doc. 2018-24595 Filed 11-8-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2018-0066]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, Department of Homeland Security (DHS).

ACTION: Committee Management; notice of Federal Advisory Committee meeting.

SUMMARY: The DHS Data Privacy and Integrity Advisory Committee will meet on Monday, December 10, 2018, in Washington, DC. The meeting will be open to the public.

DATES: The DHS Data Privacy and Integrity Advisory Committee will meet on Monday, December 10, 2018, from 1:00 p.m. to 4:00 p.m. Please note that the meeting may end early if the Committee has completed its business.

ADDRESSES: The meeting will be held both in person in Washington, DC at 90 K Street NE, 12th Floor, Room 1204, Washington, DC 20002, and via online forum (URL will be posted on the