FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Schiff & Co. submitted a citizen petition dated October 16, 2008 (Docket No. FDA–2008–P–0560), under 21 CFR 10.30, requesting that the agency determine whether MESANTOIN (mephenytoin) Tablets, 100 mg, was withdrawn from sale for reasons of safety or effectiveness. MESANTOIN (mephenytoin) Tablets, 100 mg, is the subject of NDA 6–008, held by Novartis and initially approved on October 23, 1946. MESANTOIN is indicated to control grand mal, local, Jacksonian, and psychomotor seizures in patients who have been refractory to less toxic anticonvulsants. In a letter dated January 13, 2000, Novartis notified FDA that MESANTOIN (mephenytoin) Tablets, 100 mg, was being discontinued and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that MESANTOIN (mephenytoin) Tablets, 100 mg, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that MESANTOIN (mephenytoin) Tablets, 100 mg, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list MESANTOIN (mephenytoin) Tablets, 100 mg, 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. ANDAs that refer to MESANTOIN (mephenytoin) Tablets, 100 mg, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. 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 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28872 Filed 12–2–09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2009–0138]

Homeland Security Advisory Council

AGENCY: The Office of Policy, DHS.

ACTION: Notice of Cancellation of the Homeland Security Advisory Council Federal Advisory Committee Meeting.

SUMMARY: The meeting of the Homeland Security Advisory Council, scheduled for December 4, 2009 from 3 to 4 p.m. EST is cancelled. Notice of this meeting was published in the November 10, 2009 **Federal Register** (Volume 74, Number 216) at DHS–2009–0138.

FOR FURTHER INFORMATION CONTACT: Contact the HSAC staff at 202–447–3135 or *hsac@dhs.gov.*

SUPPLEMENTARY INFORMATION: The HSAC provides independent advice to the Secretary of the Department of Homeland Security to aide in the creation and implementation of critical and actionable policies and capabilities across the spectrum of homeland security operations. The HSAC periodically reports, as requested, to the Secretary, on such matters. Notice of cancellation of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended, 5 U.S.C. App.

Dated: November 25, 2009.

Becca Sharp,

Executive Director, Homeland Security Advisory Committee.

[FR Doc. E9–28861 Filed 12–2–09; 8:45 am]

BILLING CODE 9010–9M–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Application-Permit-Special License Unlading-Lading-Overtime Services

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

ACTION: 30-Day notice and request for comments; Extension of an existing information collection: 1651–0005.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Application-Permit-Special License Unlading-Lading-Overtime Services (Form 3171). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 50811) on October 1, 2009, 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 1320.10.

DATES: Written comments should be received on or before January 4, 2010.

ADDRESSES: Interested persons are invited to submit written comments on the 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 *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the