''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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, are the subject of approved NDA 21–729 held by Otsuka Pharmaceutical Company, Limited (Otsuka). ABILIFY (aripiprazole) is indicated for the treatment of schizophrenia, for the acute and maintenance treatment of manic and mixed episodes associated with bipolar I disorder, as an adjunctive therapy to either lithium or valproate for the acute treatment of manic and mixed episodes associated with bipolar I disorder, for use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder, for the treatment of irritability associated with autistic disorder, and for the acute treatment of agitation associated with schizophrenia or bipolar I disorder, manic or mixed.

FDA approved the NDA for ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, including the 20-mg and 30-mg strengths, on June 7, 2006. Otsuka has never marketed the 20-mg and 30-mg strengths of ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, and the 20-mg and 30-mg strength orally disintegrating tablets are listed in the ''Discontinued Drug Product List'' of the Orange Book.

Rakoczy Molino Mazzochi Siwik LLP submitted a citizen petition dated May 29, 2008 (Docket No. FDA–2008–P–0330), under 21 CFR 10.30, requesting that the agency (1) determine that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were discontinued from sale for reasons unrelated to safety and efficacy and (2) accept ANDAs for aripiprazole orally disintegrating tablets, 20 mg and 30 mg, and determine that such ANDAs are eligible for approval if all other legal and regulatory requirements are met. After considering the citizen petition and reviewing agency records, FDA has determined that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. To date, Otsuka has not marketed ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg. In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The petitioner identified no data or other information suggesting that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were withdrawn from sale as a result of safety or effectiveness concerns. FDA has reviewed its files for records concerning the withdrawal of ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg. There is no indication that Otsuka's decision not to market ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, commercially is a function of safety or effectiveness concerns, and no information has been submitted to the docket concerning the reason for which ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were withdrawn from sale. FDA's independent evaluation of relevant information has uncovered nothing that would indicate that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA has determined that ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 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 ABILIFY DISCMELT (aripiprazole) orally disintegrating tablets, 20 mg and 30 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products 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. E9–28871 Filed 12–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0560]

Determination That MESANTOIN (Mephenytoin) Tablets, 100 Milligrams, Was 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) is announcing its determination that MESANTOIN (mephenytoin) Tablets, 100 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for mephenytoin tablets, 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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 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]

BILLING CODE 4160–01–S

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