

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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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under 21 CFR 10.30, requesting that the agency determine whether MESANTOIN (mephenytoin) Tablets, 100 mg, was withdrawn from sale for reasons of safety or effectiveness.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FDA has reviewed its records and, under § 314.161, has determined that MESANTOIN (mephenytoin) Tablets, 100 mg, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that MESANTOIN (mephenytoin) Tablets, 100 mg, was withdrawn for reasons of safety or effectiveness.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data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.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]

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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 oir_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

functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Application-Permit-Special License Unlading-Lading-Overtime Services.

OMB Number: 1651-0005.

Form Number: Form 3171.

Abstract: Form 3171 is used by commercial carriers and importers as a request for permission to unlade imported merchandise, baggage, or passengers, and for overtime services of CBP officers in connection with lading or unlading of merchandise, or the entry or clearance of a vessel.

Current Actions: There are no changes to the information collection. This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 1,500.

Estimated Number of Annual Responses per Respondent: 266.

Estimated Number of Total Annual Responses: 399,000.

Estimated Time per Response: 8 minutes.

Estimated Total Annual Burden Hours: 51,870.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

Dated: November 27, 2009.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. E9-28854 Filed 12-2-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5285-N-37]

Notice of Proposed Information Collection: Comment Request; Multifamily Default Status Report

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 1, 2010.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410; e-mail Lillian_L_Deitzer@HUD.gov or telephone (202) 402-8048.

FOR FURTHER INFORMATION CONTACT: Howard Mayfield, Deputy Director, Office of Multifamily Asset Management, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410; telephone (202) 402-2558 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Multifamily Default Status Report.

OMB Control Number, if applicable: 2502-0041.

Description of the need for the information and proposed use: Mortgagees use this information collection to notify HUD that a project owner is more than 30 days past due on a mortgage payment and to elect to assign a mortgage to the Department (per regulations at 24 CFR part 207.256). To avoid an assignment of mortgage to HUD, which costs the Government millions of dollars each year, HUD and the mortgagor may develop a plan for reinstating the loan since HUD uses the information as an early warning mechanism. HUD Field Office and Headquarters staff use the data to (a) monitor mortgagee compliance with HUD's loan servicing procedures and assignments; and (b) avoid mortgage assignments in the future. This information is submitted electronically via the Internet.

Agency form numbers, if applicable: HUD-92426.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of burden hours is 1,256. The number of respondents is 63, the number of responses is 7,542, the frequency of response is 120, and the burden hour per response is 10 minutes.

Status of the proposed information collection: Extension of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: November 30, 2009.

Ronald Y. Spraker,

Acting General Deputy Assistant Secretary for Housing—Federal Housing Commissioner. [FR Doc. E9-28888 Filed 12-2-09; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

National Environmental Policy Act (NEPA) Implementing Procedures

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of proposed change to the Departmental Manual; request for comments.

SUMMARY: The Department of the Interior (Department) proposes to