

deposits; these items must be deposited by 4 p.m. Eastern Time.

+ Local Federal Reserve Bank checks; these items must be presented before 3:00 p.m. Eastern Time.

+/- *Immediate-settlement* ACH transactions; these transactions include ACH return items and check-truncation items.

Post at 5:30 p.m. Eastern Time:

+/- *FedACH SameDay service return transactions.*

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Reserve Bank Operations and Payment Systems under delegated authority, June 16, 2010.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 2010-15276 Filed 6-23-10; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

Notice of Availability of the Draft Environmental Impact Statement for Improvements to the Calexico West Port of Entry, Calexico, CA

AGENCY: Public Buildings Service, GSA.

ACTION: Notice of Availability and public hearing for the Draft Environmental Impact Statement.

SUMMARY: The General Services Administration (GSA) announces the availability of the Draft Environmental Impact Statement (EIS) for Improvements to the Calexico West Port of Entry, Calexico, California, for public review and comment. The EIS provides GSA and its stakeholders an analysis of the environmental impacts resulting from ongoing operations as well as reasonable alternatives for renovation, replacement, and continued operation of the Calexico West Port of Entry, located in south-central California.

DATES: Comments on the Draft Environmental Impact Statement may be submitted during the public comment period, which will commence with the U.S. Environmental Protection Agency's publication of the **Federal Register** Notice of Availability for this document and end on August 18, 2010. Comments may be submitted in writing, orally, or by electronic mail to the General Services Administration at the address, phone number, or e-mail listed below. Oral or written comments may also be submitted at public meetings to be held on June 22 and July 14, 2010, between 3 and 7 p.m., at the Calexico City Hall, 608 Heber Avenue, Calexico, California. Comments submitted will be

considered in preparation of the Final Environmental Impact Statement.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Smith, GSA Regional Environmental Quality Advisor, Portfolio Management Division, Capital Investment Branch (9P2PTC), U.S. General Services Administration, 880 Front Street, Room 4236, San Diego, California 92101, (619) 557-6169 or via e-mail to greg.smith@gsa.gov. Oral and written comments may also be submitted at the public hearing described in the **DATES** section. Requests for copies of the Draft Calexico West Port of Entry EIS or other matters regarding this environmental review should be referred to Greg Smith at the address above.

SUPPLEMENTARY INFORMATION: A notice of availability will be mailed to all agencies, organizations, and individuals who participated in the scoping process or were identified during the EIS process. GSA has distributed copies of the Draft Calexico West Port of Entry EIS to appropriate Congressional members and committees, the state of California, American Indian tribal governments, local county governments, other Federal agencies, and other interested parties who have already requested copies.

The Draft EIS was prepared pursuant to the National Environmental Policy Act of 1969 (NEPA) [42 U.S.C. 4321 *et seq.*] and the Council on Environmental Quality NEPA regulations [40 CFR part 1500]. GSA proposes to continue operating the Calexico West Port of Entry, which is located in Calexico in south-central California. GSA has identified and assessed several design options for the renovation, replacement, and continued operation of the Calexico West Port of Entry. In addition, GSA analyzed the No Action Alternative in which GSA would continue the status quo, that is, operate the port of entry in its current configuration, with only minor planned upgrades.

The Draft Calexico Port of Entry EIS identifies the expected environmental impacts from facility operations for each alternative. For each alternative, impact discussions are presented by resource area (*e.g.*, land use, geology and soils) or topic area (*e.g.*, traffic, environmental justice).

After the public comment period, which ends August 18, 2010, GSA will consider the comments received, revise the Draft EIS, select a preferred alternative, and issue a Final EIS. GSA will consider the Final EIS, along with other economic and technical considerations, to make a decision on the appropriate course for

improvements at the Calexico West Port of Entry.

ADDRESSES: Comments may be submitted in writing to: Mr. Greg Smith, Regional Environmental Quality Advisor, Portfolio Management Division, Capital Investment Branch (9P2PTC), U.S. General Services Administration, 880 Front Street, Room 4236, San Diego, California 92101, or via e-mail to greg.smith@gsa.gov. Oral and written comments may also be submitted at the public meetings described in the **DATES** section. Copies of the Draft Calexico Environmental Impact Statement may be downloaded from <http://www.gsa.gov/nepalibrary>. Other matters regarding this environmental review should be referred to Greg Smith at the address above.

Dated: June 10, 2010.

Samuel R. Mazzola,
*Director, Portfolio Management Division,
Public Building Service, Pacific Rim Region.*

[FR Doc. 2010-15299 Filed 6-23-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 26, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0298. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Threshold of Regulation for Substances Used in Food-Contact Articles—(OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j), (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive that meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or

an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical

composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of April 9, 2010 (75 FR 18209), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	7	1	7	48	336

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past 3 years. The annual hours per response reporting estimate of 48 hours is based on information received from representatives of the food packaging and processing industries and agency records.

FDA estimates that approximately 7 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910-0495) in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of

food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at <http://www.cfsan.fda.gov>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: June 16, 2010.
David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.
 [FR Doc. 2010-15302 Filed 6-23-10; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2010-N-0273]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulations

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain