Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30837 Filed 12–24–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0652]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of Participation

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 information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for filing a notice of participation with FDA.

DATES: Submit written or electronic comments on the collection of information by February 27, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191)—Extension

Section 12.45 (21 CFR 12.45) issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation, state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the pre-hearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	8	1	8	3	24

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

The burden estimates for this collection of information are based on agency records and experience over the past 3 years.

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Dated: December 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30839 Filed 12–24–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2008–1229]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice seeking public comments on MARPOL Reception Facilities.

SUMMARY: The Chemical Transportation Advisory Committee (CTAC), through its Working Group on the International Convention for the Prevention of Pollution from Ships (MARPOL) Annex, has been tasked with providing comment and recommendations to the U.S. Coast Guard for optimizing domestic MARPOL port reception facilities. CTAC is a committee formed under the authority of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. (Pub. L. 92–463). To assist and complement CTAC's efforts, the Coast Guard is hereby seeking comments from the public on MARPOL reception facilities in the U.S. The Coast Guard is specifically interested in identifying all issues that negatively impact MARPOL implementing regulations for port reception facilities; and recommendations to address those issues.

CTAC Tasking: The original Task Statement that was provided to CTAC at the April 24, 2008 meeting in Washington, DC, included the following:

1. Provide comments and recommendations as necessary on: (To be completed by the Spring of 2009)

- Impact, if any, on MARPOL compliance caused by a variance in disposal costs;
- Impact, if any, on MARPOL compliance caused by vessels having to shift berths to complete transfers;
- Plan to document MARPOL reception facility services required and received through an advanced notice of arrival and departure report;
- Disposal of residues at other than those facilities receiving the cargo related to those residues. Vessels currently have limited information on availability of Annex I and Annex II facilities at subsequent ports of call;
- Level of consistency in disposal procedures in fulfillment of federal, state and local MARPOL waste disposal requirements as well as operational variances among facilities. For example, in fulfillment of state requirements, some facilities may request pre-identification of constituents in Annex I as well as Annex II residues. Additionally, facilities themselves have differing disposal procedures; and,
- Feasibility of simultaneous MARPOL and cargo transfers at every facility. According to vessel operators, some facilities prohibit simultaneous discharge of MARPOL residues and cargo transfers thereby causing delays.

2. Provide a final report in items listed above, a recommended way-ahead to implement any recommendations (e.g., proposed changes to MARPOL and/or domestic regulations) and the corresponding implementing language. (To be completed by the fall of 2009)

Seeking Public Comment: Possible areas of concern for stakeholders may include:

- Conflicts with other regulations;
- Disposal cost issues at ports/terminals;
- Requirement for lab analysis of Annex I or II wastes;
- Segregation of Annex V wastes; and
- Additional burden, if any, of adopting standardized Advance Notice Forms (ANF) and/or Waste Delivery Receipt (WDR) forms adopted by the International Maritime Organization.

Public comments that are received will assist and complement CTAC's efforts. CTAC's MARPOL Annex working group is scheduled to meet in February 2009. Comments must be received by January 31, 2009 in order to be considered.

ADDRESSES: The public may address comments via USPS, e-mail or FAX, to Mr. James Prazak, CTAC Chairman, C/O The Dow Chemical Company, 2301 N. Brazosport Blvd., B–122, Freeport, TX 77541–3257. FAX (979) 238–9737, E-mail: *jprazak@dow.com*. The Coast Guard requests that copies of comments be sent HQ, U.S. Coast Guard, CG–5442, ATTN: Commander Michael Roldan, 2100 Second Street, SW., Washington, DC 20593–0001. Fax: 202–372–1906, E-mail: *luis.m.roldan@uscg.mil*.

FOR FURTHER INFORMATION CONTACT: Commander Michael Roldan, telephone 202–372–1130, e-mail: *luis.m.roldan@uscg.mil*, or David Condino, MARPOL COA Project Manager, telephone 202–372–1145, e-mail: *david.a.condino@uscg.mil*.

SUPPLEMENTARY INFORMATION: Notice seeking public comment is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463).

Public Meeting: A separate Notice will be given regarding the next CTAC meeting at which time the Coast Guard will seek to discuss such public comments and the recommendations of CTAC. This will be a public meeting and instructions will be provided for those wishing to make oral presentations at the meeting and/or wishing to provide written comments.

Dated: December 19, 2008.

J. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. E8–30805 Filed 12–24–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2004–19621]

Dry Cargo Residue Discharges in the Great Lakes; Preparation of Environmental Impact Statement

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent; request for comments; notice of public scoping meeting.

SUMMARY: The Coast Guard announces its intent to prepare a new Environmental Impact Statement (EIS) for the next phase of this rulemaking. The new EIS will tier off the first EIS, which was prepared in support of the interim rule published in September 2008. Under the interim rule, the discharge of bulk dry cargo residue is allowed to continue in limited areas of the Great Lakes and under certain conditions. The Coast Guard plans to issue a final rule that may modify the interim rule and add new conditions for discharges. The new EIS will support the final rule. This notice requests public comments and begins a public scoping process to help determine the scope of issues to be addressed in the new EIS.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before March 30, 2009 or reach the Docket Management Facility by that date. The public scoping meeting will be held on January 28, 2009, from 1 p.m. to 5 p.m. Comments and related material must reach the Docket Management Facility on or before March 30, 2009.

ADDRESSES: The public scoping meeting will be held at the Hotel Blake, 500 South Dearborn, Chicago, IL 60605. The