

submissions may be made to the contact person on or before March 28, 2007. Oral presentations from the public will be scheduled between approximately 4 p.m. to 5 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before by March 20, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested person regarding their request to speak by March 21, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Carlos Pena at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 8, 2007.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0080]

#### Draft Guidance for Industry on Indexing Structured Product Labeling; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Indexing Structured Product Labeling." This guidance explains that the Center for Drug Evaluation and Research (CDER) will

index structured product labeling (SPL) in the product labeling for human drugs. This guidance also makes recommendations to industry on how to request a change to the indexing information in the SPL.

**DATES:** Submit written or electronic comments on the draft guidance by June 18, 2007. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Laurie Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20993-0002, [laurie.burke@fda.hhs.gov](mailto:laurie.burke@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Indexing Structured Product Labeling." This guidance explains that FDA's CDER will index SPL in the product labeling for human drugs. This guidance also makes recommendations to industry on how to request a change to the indexing information in the SPL.

A Health Level Seven (HL7)<sup>1</sup> standard, SPL is used for electronically exchanging the content of labeling and other regulated product information using the extensible markup language. The SPL standard enables the inclusion of indexing elements with product labeling. These machine-readable identifiers enable users, such as clinical decision support tools and electronic prescribing systems, to rapidly search and sort product information found in product labels. Indexing the SPL will

<sup>1</sup> See <http://www.hl7.org>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

greatly facilitate the efficient communication of important drug information to the public, helping create a more robust nationwide system for promoting the safe and effective use of drugs.

After completing a 6-month pilot project evaluating how best to add indexing elements, FDA determined that the most efficient strategy is for FDA, not individual applicants, to index the SPL using a phased approach. We will index the pharmacological class during the first phase. We are adding pharmacologic class first because: (1) It is important for the safe use of drugs, (2) it is necessary for making future indexing meaningful (e.g., drug interactions), and (3) this choice leverages existing FDA resources. After pharmacologic class, we will be seeking public input on which indexing elements should be added in future phases.

The draft guidance also recommends that applicants submit any questions regarding existing indexing, including any requests to add or revise an indexing element, to CDER ([sp@fda.hhs.gov](mailto:sp@fda.hhs.gov)). Inquiries and requests will be forwarded to the appropriate FDA personnel who will consider them and make the appropriate change in the SPL.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on indexing SPL. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 7, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-4881 Filed 3-16-07; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2007-27492]

### Chemical Transportation Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Chemical Transportation Advisory Committee (CTAC), its Subcommittees on Hazardous Cargo Transportation Security (HCTS), the National Fire Protection Association (NFPA) 472 Standard, and Outreach, as well as its Working Group on Barge Hazard Communication will meet to discuss various issues relating to the marine transportation of hazardous materials in bulk. These meetings will be open to the public.

**DATES:** Both the Subcommittee on Outreach and the Working Group on Barge Hazard Communication will meet on Tuesday, April 10, 2007, from 8 a.m. to 12 p.m. and the NFPA 472 Subcommittee will meet on Tuesday, April 10, 2007, from 12:30 p.m. to 4:30 p.m. The NFPA 472 Subcommittee will meet on Wednesday, April 11, 2007, from 8 a.m. to 12 p.m. and the Subcommittee on HCTS will meet on Wednesday, April 11, 2007, from 12:30 p.m. to 4:30 p.m. CTAC will meet on Thursday, April 12, 2007, from 9 a.m. to 3:30 p.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before April 3, 2007. Requests to have a copy of your material distributed to each member of the Committee should reach the Coast Guard on or before April 3, 2007.

**ADDRESSES:** The meetings of the Subcommittees on Outreach, NFPA 472 and HCTS and the Working Group on Barge Hazard Communication will be held at the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. The CTAC meeting will be held at the Boston Marriott Quincy, 1000 Marriott Drive, Quincy, MA 02269. Send written material and requests to make oral presentations to Commander Richard Raksnis, Executive Director of CTAC, Commandant (CG-3PSO-3), U.S. Coast Guard

Headquarters, 2100 Second Street SW., Washington, DC 20593-0001 or E-mail: [CTAC@comdt.uscg.mil](mailto:CTAC@comdt.uscg.mil). This notice is available on the Internet at <http://dms.dot.gov>.

**FOR FURTHER INFORMATION CONTACT:** Commander Richard Raksnis, Executive Director of CTAC, or Ms. Sara Ju, Assistant to the Executive Director, telephone 202-372-1425, fax 202-372-1926.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

#### Agenda of the Outreach Subcommittee Meeting on Tuesday, April 10, 2007

- (1) Introduce Subcommittee members and attendees.
- (2) Finalize the poster presentation for the Responsible Care Conference in May, 2007.
- (3) Discuss outreach efforts on issues of barge emissions and vapor control systems.

#### Agenda of the Barge Hazard Communication Working Group, April 10, 2007

- (1) Introduce Working Group members and attendees.
- (2) Draft letter for voluntary compliance with the 24-hour contact number.
- (3) Develop future Working Group plans.

#### Agenda of the NFPA 472 Subcommittee Meeting on Tuesday, April 10, 2007

- (1) Introduce Subcommittee members and attendees.
- (2) Complete first draft of proposed chapter describing competencies of responders to marine non-tank vessel incidents, for future incorporation into the NFPA 472 Standard, *Professional Competence of Responders to Hazardous Materials Incidents*.

#### Agenda of the NFPA 472 Subcommittee Meeting on Wednesday, April 11, 2007

- (1) Introduce Subcommittee members and attendees.
- (2) Begin work on second draft of chapter describing competencies of responders to marine non-tank vessel incidents.
- (3) Discuss future plans for the Subcommittee.

#### Agenda of the Subcommittee on Hazardous Cargo Transportation Security (HCTS) on Wednesday, April 11, 2007

- (1) Introduce Subcommittee members and attendees.

(2) Discussion on updates to the Maritime Transportation Security Act (MTSA) regulations.

(3) Discuss Coast Guard Certain Dangerous Cargo (CDC) security project.

#### Agenda of CTAC Meeting on Thursday, April 12, 2007

- (1) Introduce Committee members and attendees.
- (2) Status report presentation from the CTAC HCTS Subcommittee to include discussion and vote on comments to the MTSA regulations.
- (3) Status report presentation from the CTAC Outreach Subcommittee.
- (4) Status report presentation from the CTAC Barge Hazard Communication Working Group.
- (5) Status report presentation from the CTAC MARPOL Annex II Working Group.
- (6) Status report presentation from the NFPA 472 Subcommittee.
- (7) Presentation on the Transportation Worker Identification Credential (TWIC) Program.
- (8) Presentation on the Marine Chemist Program.
- (9) Presentation on LNG deepwater port issues.
- (10) Update on Coast Guard regulatory projects.

#### Procedural

These meetings are open to the public. Please note that the meetings may close early if all business is finished. At the discretion of the Chair, members of the public may make oral presentations during the meetings generally limited to five minutes. If you would like to make an oral presentation at a meeting, please notify the Executive Director and submit written material on or before April 3, 2007. If you would like a copy of your material distributed to each member of the Committee in advance of a meeting, please submit 25 copies to the Executive Director (see **ADDRESSES**) no later than April 3, 2007.

#### Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, telephone the Executive Director as soon as possible.

Dated: March 8, 2007.

**J.G. Lantz,**

*Director of National and International Standards, Assistant Commandant for Prevention.*

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