6. What action should FDA take when companies disseminate violative promotional material to consumers?

For most prescription drugs and all devices, there is no requirement that companies submit their promotional materials to FDA before using them, and the U.S. Constitution limits the agency's ability to preclear promotional materials. Rather, companies must submit prescription drug promotional pieces at the time of their initial use in public. Device promotional pieces are not subject to a submission requirement. Under section 502(n) of the act, FDA can require that sponsors obtain preapproval of prescription drug advertisements only in ''extraordinary circumstances.'' As a result, FDA's review of promotional materials is almost wholly post hoc, (i.e., after the materials have already appeared in public). Consequently, any enforcement action that FDA takes will also be post hoc.

Most of FDA's enforcement actions ask sponsors to stop using the violative materials. In some cases, for both professional- and consumer-directed pieces, FDA also asks sponsors to run corrective advertisements or issue corrective promotional materials to remedy misimpressions created by false or misleading materials. The agency is interested in hearing views on this type of enforcement approach for consumer-directed promotional materials as well as other enforcement approaches that might protect the public health.

## IV. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15. The Commissioner will designate a presiding officer, who will be accompanied by senior management from the Office of the Commissioner, the Center for Biologics Evaluation and Research, CDER, CDRH, and the Center for Veterinary Medicine.

Persons who wish to make an oral presentation during the part 15 hearing must file a written or electronic notice of participation with the Division of Dockets Management (see *Addresses*). To ensure timely handling, any outer envelope or subject heading should be clearly marked with the docket number found in brackets in the heading of this document along with the statement ''Consumer-Directed Promotion of Medical Products.'' Groups should submit two written copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation (including the specific discussion questions that will be addressed); and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. FDA asks that participants set aside both days of the meeting so that the agency can group presentations on similar topics. The agency will let the participants know as soon as possible the time and date the participant is scheduled to present. FDA may also ask participants to rank order presentation topics, and FDA may need to restrict the time allotted to each participant. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Division of Dockets Management under the docket number found in brackets in the heading of this document.

Because of limited seating at the conference facility, FDA requests that organizations restrict their number of attendees at the meeting to five.

Under § 15.30, the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see *For further information contact*).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

## V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic notices of participation and comments for consideration at the hearing. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions to which they refer (see section III of this document). Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number at 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. Transcripts of the hearing also will be available for review at the Division of Dockets Management.

## VI. Transcripts

The transcript of the hearing will be available 30 days after the hearing on the Internet at *http://www.fda.gov/ohrms/dockets*, and orders for copies of the transcript can be placed at the meeting or through the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Dated: September 6, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–18040 Filed 9–9–05; 8:52 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

**[DHS–2005–0061]**

### Data Privacy and Integrity Advisory Committee

**AGENCY:** Office of the Secretary, Department of Homeland Security.

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The notice announces the date, time, location, and agenda for the next meeting of the Department of Homeland Security Data Privacy and Integrity Advisory Committee. This meeting will include a partially closed session.

**DATES:** This meeting will be held on Wednesday, September 28, 2005, in Bellingham, Washington.

**ADDRESSES:** The Department of Homeland Security Data Privacy and Integrity Advisory Committee meeting will be held in the Ballroom at the Hotel Bellwether, One Bellwether Way, Bellingham, Washington, 98225. If you wish to submit comments, you must do so by September 20, 2005. Comments must be identified by DHS–2005–0061 and may be submitted by *one* of the following methods:

- *EPA Federal Partner EDOCKET Web site: http://www.epa.gov/feddocket.* Follow instructions for submitting comments on the Web site.
- *E-mail: PrivacyCommittee@dhs.gov*. Include docket number in the subject line of the message.
- *Fax:* 571–227–4171.
- *Mail:* Ms. Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Arlington, VA 22202.

*Instructions:* All submissions received must include the Department of Homeland Security and DHS–2005–0061, the docket number for this action. All comments received will be posted without change to *http://www.epa.gov/feddocket*, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket*. You may also access the Federal eRulemaking Portal at *http://www.regulations.gov*.

**ADDRESSES:** Persons who are unable to attend or speak at the meeting may submit comments at any time.

- E-mail: PrivacyCommittee@dhs.gov.
- Fax: (571) 227–4171.
- Mail: Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Arlington, VA 22202.

All comments received will be posted without change to *http://www.dhs.gov/privacy*, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Nuala O'Connor Kelly, Chief Privacy Officer, or Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Arlington, VA 22202 by telephone (571) 227–3813, by facsimile (571) 227–4171, or by e-mail *PrivacyCommittee@dhs.gov*.

**SUPPLEMENTARY INFORMATION:** The Department of Homeland Security (DHS) Data Privacy and Integrity Advisory Committee (Committee) will be meeting on Wednesday, September 28, 2005, in the Ballroom at the Hotel Bellwether, One Bellwether Way, Bellingham, Washington, 98225. The meeting will begin at 8:30 a.m. and continue until 5 p.m. Although most of the meeting is open to the public, there will be a closed session between 12:30 p.m. and 2 p.m., during which Committee members will receive a sensitive briefing regarding screening programs proposed for the Transportation Security Administration's Secure Flight Program.

In the morning, the Committee will receive a report from the Chief Privacy Officer of DHS, the Federal Privacy Commissioner of Canada, and the Assistant Administrator for the Secure Flight program of the Transportation Security Administration (TSA). Reports from two of the four subcommittees, and a panel presentation about the use of radio frequency identification technology, will conclude the morning session. In the afternoon, the remaining two subcommittees will report to the Committee, and there will be a panel discussion about risk-based analysis and privacy from privacy and technology experts.

Public comments will be accepted during the meeting, between 4:30 p.m. and 5 p.m., All those who wish to testify during this time may register in advance or sign-up on the day of the meeting. In order to allow as many people as possible to testify, witnesses should limit their remarks to three minutes. Due to limited seating, any member of the public who wishes to attend the public session should provide his or her name no later than 12 p.m. E.S.T., Friday, September 23, 2005, to Rebecca J. Richards via email at *PrivacyCommittee@dhs.gov*, or via telephone at (571) 227–3813.

Photo identification will be required for entry on the day of the meeting to verify those individuals who have registered for the public session, and everyone who plans to attend should be present and seated by 8:15 a.m., or 1:45 p.m., if only attending the afternoon session. Registration information required for attendance will be used for verification purposes on the day of the meeting. Attendance information, including names of members of the public attending, may be made public as part of the official meeting minutes.

Persons with disabilities who require special assistance should indicate this in their admittance request and are encouraged to identify anticipated special needs as early as possible.

Although every effort will be made to accommodate all members of the public, seating is limited and will be allocated on a first-come, first-served basis.

**Basis for Closure**

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended, 86 Stat. 770, the Secretary of Homeland Security has determined that a portion of this Privacy Advisory Committee meeting, as referenced above, is excluded from the Open Meetings requirement pursuant to the authority contained in 5 U.S.C. 552b(c)(9)(B).

Dated: September 9, 2005.

**Nuala O'Connor Kelly,**

*Chief Privacy Officer.*

[FR Doc. 05–18264 Filed 9–12–05; 8:45 am]

**BILLING CODE 4410–10–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[CGD07–05–115]**

### Announcement of Public Hearing Regarding the Shakett Creek Pedestrian Bridge, Nokomis, FL Formerly Known as the Shakett Creek Railroad Bridge

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of public hearing.

**SUMMARY:** The U.S. Coast Guard will hold a public hearing at the Venice High School, 1 Indian Avenue, Venice, Florida 34285 to provide the Shakett Creek Pedestrian Bridge owner, waterway users and other interested persons the opportunity to offer evidence and be heard as to whether any alterations of the Shakett Creek Pedestrian Bridge in Nokomis, Florida are necessary to provide reasonably free, safe and unobstructed passage for waterborne traffic.

**DATES:** The public hearing will be held at 7 p.m., October 12, 2005.

**ADDRESSES:** The hearing will be held at the Venice High School, 1 Indian Avenue, Venice, Florida 34285. Written comments may be submitted to Commander (obr), Seventh Coast Guard District, 909 SE 1st Avenue, Room 432,