

interested in hearing about research by other persons and organizations that provides insight into the effects that consumer-directed promotion has on the public health. The agency is also interested in research on the groups most affected by consumer-directed promotion, including patients, caretakers, physicians, physician assistants, nurses, pharmacists, managed care organizations, and insurers.

**Date and Time:** The public meeting will be held on September 22, 2003, from 9 a.m. to 5 p.m., and on September 23, 2003, from 9 a.m. to 5 p.m. Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to FDA by close of business on September 10, 2003.

Persons interested in presenting research should send requests and abstracts in writing to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville MD, 20852, by close of business on August 29, 2003.

**Location:** The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594. (Phone: 202-314-6421; Metro: L'Enfant Plaza station on the green, yellow, blue, and orange lines). See: <http://ntsb.gov/events/newlocation.htm>. (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**.)

**Registration and Requests for Presentation:** No registration is required to attend the meeting. Seating will be on a first-come, first-served basis. If you wish to present research during the public meeting, please submit your request and an abstract of your presentation to the Division of Dockets Management (see *Date and Time*). Requests should be identified with the docket number listed in the heading of this document. Transcripts of the meeting will be available for review at the Division of Dockets Management.

**For Information Regarding This Notice:** Rose Cunningham, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5468, e-mail: [cunninghamr@cder.fda.gov](mailto:cunninghamr@cder.fda.gov). If you need special accommodations due to a disability, please inform the contact person.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

Part of FDA's Division of Drug Marketing, Advertising and Communication's (DDMAC) mission is to protect public health by helping to ensure that prescription drug promotion directed to professionals and consumers is truthful, contains balanced risk and benefit information, and is accurately communicated. Increased spending on consumer-directed (also called direct to consumer promotion or DTC promotion) promotion, particularly broadcast advertisements, has stimulated public debate about its value or harm to the public. Proponents argue that DTC promotion is of educational value, will improve the physician-patient relationship, will make consumers aware of conditions they have that could benefit from treatment, would potentially improve health care, and could lower long-term health care costs through early recognition and treatment. Opponents contend that: Consumers do not have the expertise to accurately evaluate and comprehend prescription drug advertising, DTC promotion is typically misleading because it fails to adequately communicate risk information, DTC promotion will damage the physician-patient relationship, it will increase drug prices, lead to over-medication and drug abuse, and it will lead to use of the most costly alternatives. FDA needs to consider all points of view in the public debate.

In the **Federal Register** of August 12, 1997 (62 FR 43171), FDA announced the availability of a draft guidance for industry concerning DTC broadcast advertisements. The draft guidance was intended to describe how advertisers could fulfill their obligations under the regulations to provide consumers with necessary risk information in connection with prescription-drug advertisements broadcast, through general public media such as radio, television, and telephone communications systems. The prescription drug advertising regulations under part 202.1 (21 CFR 202.1) distinguish between print and broadcast advertisements. In addition to presenting a fair balance between information relating to side effects and contraindications and information relating to the effectiveness of the drug, print advertisements must include a "brief summary," that generally includes all risks cited in the product's approved package labeling. In contrast, advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the

presentation (this is sometimes called the "major statement"); but need not provide the brief summary, as this would generally be impractical in broadcast or telephone media. Instead these advertisements may make "adequate provision \* \* \* for dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (§ 202.1(e)(1)). The draft guidance described, and explained the rationale behind, one possible multifaceted approach that would fulfill the "adequate provision" requirement.

After considering comments received from the public, the agency revised the draft guidance and published it as a final guidance on August 9, 1999 (64 FR 43197). FDA noted that although the comments did not address the specific issue of telephone advertisements, the lack of a specific discussion concerning such advertisements may have led to the assumption that the same multifaceted approach for television and radio advertisements was also appropriate for telephone advertisements. Therefore, in the final guidance, FDA clarified its position with regard to fulfilling the "adequate provision" requirement for telephone advertisements. Aside from this clarification and the revision of introductory language to reinforce the importance in broadcast advertisements of complying with the more general requirements of the advertising regulations, there were no major revisions to the draft guidance. The final guidance and a document entitled "Consumer-Directed Broadcast Advertisements Guidance: Questions and Answers" is available on FDA's Web site at [www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm).

The agency said in the August 9, 1999, **Federal Register** notice announcing availability of the final guidance, that the agency intended to evaluate the effects of the guidance and DTC promotion, in general, on the public health. FDA said it would determine whether this guidance should be withdrawn, continued, or modified to reflect the agency's current thinking. The public meeting being announced in this document is one component of the approach the agency is taking to fulfill its commitment to this evaluation.

Another component is the research FDA has conducted on DTC promotion, including surveys of consumers in 1999 and 2002, as well as a survey of physicians in 2002 that explored how DTC promotion affects the patient-physician relationship. FDA intends to present the results of those findings at the public meeting.