hearing will be transcribed as required in § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any disabled persons requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

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).

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 until December 29, 1995.

IV. Additional Request for Information

In order to assess the costs and benefits of enhanced OTC drug product labeling, written submissions to FDA on the following topics would be helpful:

(1) How frequently do companies reprint OTC drug product labels and labeling? How frequently are labels redesigned?

(2) What are the itemized costs involved in changing OTC drug labels and labeling (e.g., design, plate, reprinting, additional colors)?

(3) If FDA were to propose a new OTC drug labeling format, what strategies could be used to lessen the cost to industry? For example, what lead time would allow manufacturers to use up existing labeling inventories?

(4) What are the benefits to consumers from improvements in OTC drug labeling?

Written comments addressing cost components should address, where applicable, one-time versus annual costs, differences in brand versus private-label costs, and implications for small businesses. The agency is most interested in cost data expressed in dollars, staff hours, and personnel (professional, technical, or support). Quantitative measures of benefits are considered most desirable, but discussions of anecdotal and/or qualitative benefits are also welcomed. Submit comments to the Dockets Management Branch (address above) identified with Docket No. 95N–0259.

Dated: August 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–20245 Filed 8–15–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0227]

Direct-to-Consumer Promotion; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding direct-to-consumer promotion of prescription drugs. The purpose of the hearing is to solicit information from, and the views of, interested persons, including health care professionals, scientists, professional groups, and consumers, on the issues and concerns relating to the promotion of prescription drug products directly to consumers through print, broadcast, and other types of media. FDA is particularly interested in hearing the views of the groups most affected by direct-to-consumer promotion, including patients, caretakers, physicians, physicians' assistants, nurses, pharmacists, managed care organizations, and insurers.

DATES: The public hearing will be held on October 18, 1995, from 8:30 a.m. to 5:30 p.m., and October 19, 1995, from 8:30 to 12:30 p.m. Submit written notices of participation by September 15, 1995. Written comments will be accepted until December 29, 1995.

ADDRESSES: The public hearing will be held at the Quality Hotel—Silver Spring, 8727 Colesville Rd., Silver Spring, MD. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 95N–0227. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has responsibility for regulating the labeling and advertising (promotional activities) for prescription drugs. Under section 201(m) of the act (21 U.S.C. 321(m), labeling is defined to include all ''written, printed, or graphic'' materials ''accompanying'' a regulated product. The Supreme Court has agreed with the agency that this definition is not limited to materials that physically accompany a product. The Court has deemed the textual relationship between the materials and the products to be fundamental (*Kordel* v. *United States*, 335 U.S. 345, 349–350 (1948)). In its regulations, FDA has given examples of things that it regards as labeling, including brochures, mailing pieces, calendars, price lists, letters, motion picture films, sound recordings, and literature (§ 202.1(l)(2) (21 CFR 202.1(l)(2)). Although the act does not define what constitutes a prescription drug ''advertisement,'' FDA generally interprets the term to include information (other than labeling) that is sponsored by a manufacturer and is intended to supplement or explain a product. This includes, for example, ''advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems'' (§ 202.1(l)(1)).

If an activity or material is considered to be either advertising or labeling, it must meet certain requirements. Labeling must contain adequate directions/information for use that is the ''same in language and emphasis'' as the product's approved or permitted labeling (21 U.S.C. 352(f)) and 21 CFR 201.100(d)). This requirement is generally fulfilled by including the full approved labeling for the product (the ''package insert'') with the promotional materials. The act specifies that, in addition to the identity of the product and its quantitative composition, advertisements must contain ''other information in brief summary relating to side effects, contraindications, and effectiveness * * *''(21 U.S.C. 352(n)). FDA further defines this latter requirement in § 202.1(e). This requirement is generally fulfilled by including the sections of the approved labeling that discuss the product's adverse event profile, contraindications, warnings, and precautions. In addition, the act and regulations specify that drugs are deemed to be misbranded if their labeling or advertising is false or misleading in any particular or fails to reveal material facts (21 U.S.C. 352(a) and 321(n) and § 202.1(e)).

A. History of Direct-to-Consumer Promotion

The practice of promoting prescription drug products directly to consumers began to gain popularity in the early 1980's. Until that time, drug

manufacturers had typically limited their promotion to health care professionals. With the onset of direct-to-consumer promotion, the effectiveness of the regulatory scheme, was called into question.

To explore the ramifications of direct-to-consumer prescription drug promotion, FDA requested a voluntary moratorium on this practice in a September 2, 1983 policy statement. During the moratorium, FDA sponsored a series of public meetings and conducted research. In 1984, a symposium, jointly sponsored by the University of Illinois and Stanford Research Institute (SRI), was held to discuss consumer-directed prescription drug advertising from a broad research and policy perspective. In the **Federal Register** of September 9, 1985 (56 FR 36677), the moratorium was withdrawn in a notice, which stated that the current regulations governing prescription drug advertising provide ''sufficient safeguards to protect consumers.''

Since 1985, FDA has applied the act and the prescription drug advertising regulations to both professional and consumer-directed promotion on a case-by-case basis. There are no regulations that pertain specifically to consumer-directed promotional materials. FDA recognizes and accounts for the differences between health care professionals and consumers as recipients of drug promotion, such as differences in medical and pharmaceutical expertise, perception of pharmaceutical claims, and information processing. For this reason, FDA has monitored direct-to-consumer promotion to help ensure that adequate contextual and risk information, presented in understandable language, is included both to fulfill the requirement for fair balance and to help the consumer accurately assess promotional claims and presentations. Additionally, in a July 1993 letter to the pharmaceutical industry, as well as in numerous prior and subsequent public presentations given by FDA staff, the agency has requested that drug manufacturers voluntarily submit proposed direct-to-consumer promotional material prior to use, allowing FDA the opportunity to review and comment upon proposed materials before they reach consumers.

B. Current Issues in Direct-to-Consumer Promotion

1. General

The repercussions of direct-to-consumer promotion have been widely discussed. Proponents argue that direct-to-consumer promotion is of educational value and will improve the physician-patient relationship, increase patient compliance with drug therapy and physician visits, and lower drug prices. Opponents contend that consumers do not have the expertise to accurately evaluate and comprehend prescription drug advertising. Opponents also argue that such promotion is misleading by failing to adequately communicate risk information, and that such promotion will damage the physician-patient relationship, increase drug prices, increase liability actions, and lead to over-medication and drug abuse. Rigorous studies are needed to assess the actual effects of direct-to-consumer promotion and to help guide future policy.

In the last few years, FDA has received a number of citizen petitions that address direct-to-consumer promotion. The positions advocated by these petitions vary considerably. One petition requests that FDA ban direct-to-consumer advertising of prescription drugs. A second petition requests that FDA not adopt or institute any significant new restrictions to existing regulations nor mandate prior approval of consumer-directed advertising. A third petition, recently updated and reissued by the petitioner, contends that consumer-directed prescription drug advertising should not be regulated under § 202.1, and it also contends that FDA should promulgate new regulations to address prescription drug advertisements directed to consumers. The petitioner further contends that, until such time as new regulations are established, FDA should issue a policy statement that prescription drug advertisements directed to the general public are exempt from the advertising regulations. Another petition, recently received by FDA, reiterates these concerns and also raises First Amendment issues. The range of actions requested in these petitions is indicative of the diversity of views regarding direct-to-consumer promotion. FDA recognizes the importance of the issues raised by these petitions, and FDA intends that one of the purposes of the public hearing will be to assist the agency in responding to these petitions.

2. Types of Direct-to-Consumer Promotion

There are three broad categories of direct-to-consumer promotion of prescription drugs: (1) ''Product-claim,'' containing safety and efficacy claims about a particular drug(s); (2) ''help-seeking,'' containing information about a disease or condition and a recommendation for the consumer to consult a health care provider, when appropriate, while excluding discussions of specific treatments or drugs; and (3) ''reminder,'' containing the name of the drug and other limited information, but excluding all representations or suggestions about the drug(s).

3. Product-Claim

Product-claim promotional materials contain safety and efficacy claims about a specific prescription drug product. The regulations require that these materials present a balanced view of the drug (§ 202.1(e)(5)(ii)). Claims of drug benefits, such as safety and efficacy, must be balanced with relevant disclosures of risks and limitations of efficacy. This balanced presentation of drug therapy is commonly referred to as ''fair balance.''

Currently, most consumer-directed product-claim materials are limited to one drug product and do not compare drugs, or classes of drugs, with each other. Proponents of this noncomparative format argue that consumers do not have the contextual knowledge required to critically evaluate comparative claims. Opponents contend that consumers could evaluate comparative claims that are properly framed and fairly balanced.

4. Help-Seeking

Help-seeking promotional materials encourage consumers with particular symptoms, conditions, or diseases to consult their doctor to discuss general treatment options, but do not mention specific prescription drug products.

If the only available treatment for a condition is a specific prescription drug product, help-seeking materials may not be employed. In such a case, materials focusing on the condition would, by implication, promote the product. In addition, help-seeking materials may not include ''linkages,'' i.e., logos, tag lines, graphics, etc., to product-specific materials. Linkages create a clear association between a disease and a prescription drug, resulting in the interpretation of the help-seeking material as product-claim material. Help-seeking materials that include linkages are regulated as product-claim materials.

As direct-to-consumer promotion has become more sophisticated, some opponents have questioned FDA's decision not to regulate help-seeking materials. They argue that even in the absence of direct linkages, many consumers are able to connect the sponsoring manufacturer with a specific prescription drug.

5. Reminder

Reminder promotional materials are a means of reinforcing name recognition and brand loyalty. When targeted toward prescribers, manufacturers anticipate that this marketing technique will increase the frequency with which a prescriber recalls the name of a drug and its clinical role. This process is expected to result in an increased number of prescriptions for the manufacturer's product. The utility of reminder materials for consumers has not been resolved. Consumers are less likely to associate the brand name of a prescription drug with its clinical function(s). Moreover, consumers generally do not make prescribing decisions. Therefore, many question the value of this marketing technique for consumers, which, by definition, fails to provide clinical information.

6. Disclosure Requirements for Print Labeling and Advertising

As described previously, the act requires that non-reminder labeling bear ''adequate directions for use'' of the product (21 U.S.C. 352(f)) and that non-reminder advertising include a ''true statement of * * * other information in brief summary relating to side effects, contraindications, and effectiveness'' (21 U.S.C. 352(n)). This statement has become known as the ''brief summary.'' These disclosure requirements are generally satisfied by reprinting the full package insert with labeling or the brief summary with advertising. However, the package insert is written in technical language intended for health care professionals and is relatively inaccessible to consumers. Consequently, the value of this information for consumers is questionable. At issue is whether the same information could be presented in a format and language more easily understood by consumers.

7. Disclosure Requirements for Broadcast Advertising

Broadcast advertisements (radio, television, or telephone communications systems) must contain a brief summary, unless ''adequate provision is made for dissemination'' of the approved labeling in connection with the presentation (§ 202.1(e)(1)). Advertisements targeted to health care professionals may meet this requirement by providing the page number for the advertised product in the *Physicians' Desk Reference* (PDR), along with a toll-free telephone number by which the professional may request a copy of the package insert. Most consumers do not have ready access to the PDR. Therefore, such a page reference would be inadequate.

Because of the difficulty of satisfying the disclosure requirement, consumer-directed broadcast advertisements have been largely limited to reminder and help-seeking advertisements. Reminder and help-seeking advertisements are exempt from the disclosure requirements. New methods of satisfying the ''adequate provision'' requirement, such as scrolling the approved product labeling following television broadcasts, continue to be explored.

Broadcast advertisements also are required to present information relating to the major risks (i.e., side effects, warnings, precautions, and contraindications) of the drug (§ 202.1(e)(1)). This disclosure is commonly referred to as the ''major statement.'' The major statement must be presented as an integral part of the broadcast advertisement and be communicated in language understood by consumers. Nevertheless, the major statement is a relatively fleeting disclosure and many have questioned the ability of the consumer to comprehend and process the information.

8. Fair Balance

As discussed earlier, the regulations require that advertisements present a fair balance of benefit and risk information. Claims of drug benefits, such as safety and efficacy, must be balanced with relevant disclosures of risks and limitations of efficacy. The regulations also require that the risk information be presented with a prominence and readability reasonably comparable to claims about drug benefits (§ 202.1(e)(7)(viii)). In consumer-directed promotion, FDA has interpreted these requirements to mean that balancing information should appear in the body copy of the promotional material in language understood by consumers. Balancing information is intended to provide a framework for the consumer to understand and evaluate drug benefit claims, allowing them to form accurate opinions about prescription drugs. These disclosures, often referred to as ''critical messages,'' also serve to facilitate and focus the physician-patient interaction.

Opponents of direct-to-consumer promotion argue that critical messages cannot provide consumers with the contextual knowledge required to assess the risks associated with the use of a prescription drug. Accordingly, they would like to see direct-to-consumer promotion halted.

9. Consumer Services

Manufacturer-sponsored patient-support programs are becoming increasingly common. These programs are highly visible to consumers and may be perceived as adding value to their therapy. Such programs offer services such as patient counseling, care giver counseling, therapy compliance tracking, and disease monitoring. These programs may allow the drug manufacturer to influence the course of drug therapy beyond the initial prescribing decision. Disclosure of the manufacturer's sponsorship is not always clear. For example, some of these services may appear to be sponsored by the patient's physician or other health care provider.

Other manufacturer-sponsored consumer services appear to be sponsored by unbiased third parties, such as disease-specific foundations. This relationship may be utilized in many ways. For instance, the foundation may disseminate manufacturer-prepared drug information to consumers on behalf of the manufacturer. Consumers may not be aware of the true source of the information, and consequently, they may not evaluate this information as critically as they would manufacturer-disseminated information. At issue is whether or not these services mislead consumers.

II. Scope of the Hearing

In light of the many complex public health issues raised by direct-to-consumer prescription drug promotion, FDA is soliciting broad public participation and comment concerning this area. FDA is particularly interested in exploring whether, and, if so, how, the agency's current regulatory approach should be modified. As direct-to-consumer promotion evolves, FDA will continue to help ensure that consumers receive timely, understandable, and accurate information about prescription drugs.

Examples of issues that are of interest to the agency include the following:

1. What is known about the effects of direct-to-consumer promotion? What effects, if any, does direct-to-consumer promotion have on the public health?

2. Does direct-to-consumer promotion oversimplify the safety and effectiveness of prescription drugs? If so, what impact does such oversimplification have on the public health?

3. Can consumers understand and accurately assess claims regarding the efficacy and safety of prescription drugs? What kind of additional information, if any, should be required

in the presentation of comparative drug claims to ensure that consumers understand and may critically evaluate them?

4. Reminder advertisements, by definition, lack contextual and risk information. What role do such advertisements play in consumer promotion? Are such advertisements useful for consumers?

5. (a) Current regulations require inclusion of a ''brief summary'' of prescribing information in print advertisements. Is this form of disclosure effective for consumers? Is it informative? Should there be alternate requirements for risk disclosure, and, if so, what should they be? (b) Current regulations require that broadcast advertisements present a ''brief summary'' of prescribing information unless adequate provision is made for the dissemination of the approved product labeling. Also required is a statement of the major risks of the product. Are these disclosure requirements effective and informative for consumers? Are there alternate types of risk disclosures that are more effective or informative? If so, what are they?

6. New technologies have spurred the growth of computer-based promotional vehicles, such as electronic bulletin boards, kiosks in pharmacies, the Internet, etc. These promotions are neither purely print nor broadcast. What disclosure requirements, in general, should be used for such consumer-directed prescription drug promotion?

7. ''Infomercials'' are program-length television or radio programs that promote prescription drugs to consumers. What restrictions and/or disclosures should be required of infomercials promoting prescription drugs to consumers?

8. To help ensure that advertisements will be in ''fair balance,'' FDA currently requests disclosure of key risk and/or limitations of efficacy information, i.e., critical messages, in consumer-directed prescription drug promotion. In general, are such disclosures effective and informative for this audience? What kinds of information should be disclosed?

9. Some manufacturer-supported direct-to-consumer promotion appears to be sponsored by independent, third-party services, such as mailings from disease-specific foundations or disease management support services. What disclosures should be required to inform consumers of the source of the communication?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) by September 15, 1995. To ensure timely handling, the outer envelope should be clearly marked with docket number 95N–0227 and the statement ''Direct-to-Consumer Hearing.'' Groups should submit two copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; brief summary of the presentation; 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. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

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 presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Dockets Management Branch under docket number 95N–0227.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (21 CFR part 10, subpart C) on the policy and procedures for electronic media coverage of public administrative proceedings. 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 required by § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any handicapped person requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

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).

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 until December 29, 1995.

Dated: August 7, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–20314 Filed 8–15–95; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Meeting

Pursuant of Pub.L. 92–463, notice is hereby given of the meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council in September 1995.

The meeting of the CSAT National Advisory Council will include a discussion of the mission and programs of the Center, policy issues and administrative, legislative, and program developments. The Council will also be performing a review of grant applications, contract proposals and procurement plans for Federal assistance; therefore a portion of this meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(3)(4) and (6) and 5 U.S.C. app. 2 10(d). Attendance by the public at the open portion of the meeting will be limited to space available. Public comments are welcome during the open session. Please communicate with the Contact person listed below for guidance.

A summary of the meeting and roster of council members may be obtained from: Ms. D. Winstead, Committee