ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Status Reporting Form for program of State Council on Developmental Disabilities	55	1	8	440

Estimated Total Annual Burden Hours: 440.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 7, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–18045 Filed 9–12–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0354]

Consumer-Directed Promotion of Regulated Medical Products; 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 on direct-to-consumer (DTC) promotion of regulated medical products, including prescription drugs for humans and animals, vaccines, blood products, and medical devices. FDA is particularly interested in hearing the views of individuals and groups most affected by DTC promotion, including consumers, patients, caregivers, health professionals (physicians, physicians' assistants, dentists, nurses, pharmacists, veterinarians, and veterinarian technicians) managed care organizations, and insurers, as well as the regulated industry. FDA is seeking input on a number of specific questions, but is interested in any other pertinent information participants in the hearing would like to share.

Dates and Times: The public hearing will be held on November 1 and 2, 2005, from 9 a.m. to 5 p.m. Submit written or electronic notices of participation by close of business on October 11, 2005. Written and electronic comments will be accepted until February 28, 2006.

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, 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 changes to the Web site after this document publishes in the **Federal Register**.)

Addresses: Written or electronic notices of participation should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or on the Internet at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Comments about the meeting or comments after the meeting should be submitted to *http://www.fda.gov/dockets/ecomments*. Written or electronic comments can be submitted to *http://www.fda.gov/oc/dockets/ecomments*. A consolidated list of all documents and other information related to the public hearing, such as the **Federal Register** notice, the agenda, public comments, and transcripts will be posted with their links, as the documents are made available, on the Center for Drug Evaluation and Research (CDER) Web site at *http://www.fda.gov/cder/ddmac*.

For further information contact: Rose Cunningham, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–443–5595, e-mail: *cunninghmar@cder.fda.gov*.

For registration to attend and/or to participate in the meeting: Seating at the hearing is limited. People interested in attending the meeting should register at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Registration is free and will be accepted on a first-come, first-served basis.

The procedures governing the hearing are found in part 15 (21 CFR part 15). Anyone wishing to make an oral presentation during the hearing must state this intention on the registration form (see *Addresses*). To participate, submit your name, title, business affiliation, address, telephone and fax numbers, and e-mail address.

A written statement also should be submitted at the time of registration for each discussion question to be addressed, with the names and addresses of all individuals who plan to participate, and the approximate 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. Individuals who have registered to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. Depending on the number of presentations, FDA may need to limit the time allotted for each presentation. FDA has identified questions and subject matter of special interest in section III of this document, but presentations do not have to be limited to those questions. Presenters should

submit to the agency two copies of each presentation given. All participants are encouraged to attend the entire 2-day meeting.

If special accommodations are needed because of a disability, the registration contact person should be informed at the time of registration.

SUPPLEMENTARY INFORMATION:

I. Background

A. Definition of Terms and Regulatory Requirements

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA has responsibility for regulating the labeling and advertising of prescription drugs and medical devices. If an activity or material is considered to be either advertising or labeling, it must meet certain requirements. The regulatory framework for prescription drug labeling and advertising is both more straightforward and more developed than is the regulatory framework for the labeling and advertising of medical devices.

Under section 201(m) of the act (21 U.S.C. 321(m)), labeling is defined as including ''all labels and other written, printed, or graphic'' materials ''upon'' or ''accompanying'' a regulated product. The term ''accompanying'' has been broadly defined by the Supreme Court (*Kordel* v. *United States*, 335 U.S. 345, 349–350 (1948)). FDA's regulations give examples of labeling materials, including brochures, mailing pieces, detailing pieces, calendars, price lists, letters, motion picture films, and sound recordings (§ 202.1 (21 CFR 202.1(1)(2))).

FDA regulates the labeling of all drugs and devices under its jurisdiction. Labeling must be truthful and nonmisleading (section 502(a) of the act (21 U.S.C. 352(a)). For human and veterinary prescription drugs, 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) and 201.105(d)). This requirement is generally fulfilled by including the full approved labeling for the product (the ''package insert'') with the promotional materials. For devices, the requirement of 21 U.S.C. 352(f) applies as well, and a device is misbranded unless its labeling bears adequate instructions for use. A device that is safe only if used under the supervision of a licensed practitioner and for which adequate instructions for use can therefore not be provided, is exempt from this requirement if, among other things, all of its labeling that purports to furnish information on the use of the device also contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which licensed practitioners can safely use the device for the purposes for which it is intended.

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 issued by, or on behalf of, a manufacturer, packer, or distributor and is intended to promote 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)).

The act specifies that, in addition to the identity of the product and its quantitative composition, prescription drug 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 frequently is 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 considered 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 section 201(a) of the act (21 U.S.C. 321(n)), and § 202.1(e)).

FDA similarly regulates advertising for restricted devices. A ''restricted device'' is a device that may be restricted to the sale, distribution, or use only with the written or oral authorization of a licensed practitioner, or in accordance with other conditions if FDA determines that there cannot otherwise be reasonable assurance of its safety and effectiveness (section 502(e) of the act) 21 U.S.C. 360j(e)). Currently, three devices are restricted by regulation. FDA also restricts devices through the approval orders granted to many class III devices (21 U.S.C. 360e(d)(1)(B)(ii)).

According to the act, a restricted device is misbranded if its advertising is false or misleading in any particular (21 U.S.C. 352(q)), or if its advertising does not contain a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications (21 U.S.C. 352(r)). There are currently no regulations establishing specific requirements for the content or format of the advertisements for restricted devices.

B. History of DTC Promotion

A summary of milestones in the history of DTC promotion, with embedded links to Web sites for additional background information, is given in this section of the document. A consolidated list of these documents and their links is available on the CDER Web site at *http://www.fda.gov/cder/ddmac*.

- In response to early instances of DTC promotion, FDA requested a voluntary moratorium on DTC promotion in a September 2, 1983, policy statement. During the moratorium, FDA sponsored a series of public meetings and conducted research.
- In the **Federal Register** of September 9, 1985 (56 FR 36677), the moratorium was withdrawn in a notice that stated that the current regulations governing prescription drug advertising provide ''sufficient safeguards to protect consumers.''
- In a July 1993 letter to the pharmaceutical industry, the agency asked drug manufacturers to voluntarily submit proposed DTC promotional material prior to use, allowing FDA the opportunity to review and comment upon proposed materials before they reach consumers.
- In the **Federal Register** of August 16, 1995 (60 FR 42581), FDA announced a part 15 hearing to be held on October 18 and 19, 1995. The agency solicited oral testimony and written responses to a series of questions concerning DTC promotion of prescription drugs. The transcripts of the public meeting are available on the CDER Web site at *http://www.fda.gov/cder/ddmac/meetings.htm*.
- In the **Federal Register** of May 14, 1996 (61 FR 24314), FDA published a notice making it clear that FDA has never required preclearance of consumer-directed prescription product promotion prior to use and also soliciting additional information to help in the development of overall policy related to consumer-directed promotion of prescription products and restricted devices. This notice is available on the CDER Web site at *http://www.fda.gov/cder/ddmac*.
- In the **Federal Register** of August 12, 1997 (62 FR 43171), FDA announced the availability of a draft guidance for industry describing ways in which consumer-directed broadcast

advertisements could make ''adequate provision'' for the dissemination of the approved or permitted labeling in connection with the broadcast ad. FDA revised the draft guidance and published it as a final guidance on August 9, 1999 (64 FR 43197). The guidance and a document entitled ''Consumer-Directed Broadcast Advertisements Guidance: Questions and Answers'' is available on CDER's Web site at *www.fda.gov/cder/guidance/index.htm*.

- In February 2004, FDA published a notice of availability and requested public comment on three draft guidances pertaining to consumer-directed promotion of medical products. Comments on these draft guidances are under consideration:

1. ''Consumer-Directed Broadcast Advertising of Restricted Devices'' available on the Center for Devices and Radiological Health (CDRH) Web site at *http://www.fda.gov/cdrh/comp/guidance/1513.pdf*.
2. ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements'' available on the CDER Web site at *http://www.fda.gov/cder/guidance/index.htm*.
3. '''Help-Seeking' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms'' available on the CDER Web site at *http://www.fda.gov/cder/guidance/index.htm*.

The public comments on these draft guidances are available at *http://www.fda.gov/ohrms/dockets*.

- FDA conducted research to examine how DTC promotion affects the patient-physician relationship. On September 22 and 23, 2003, FDA held a public meeting at which the agency and other persons and organizations presented the results of their research on DTC promotion of prescription drugs through print, broadcast, and other types of media. The agenda, presentations, and transcripts from the public meeting are posted on the CDER Web site at *http://www.fda.gov/cder/ddmac/DTCmeeting2003.html*.
- On November 19, 2004, FDA published the results of its research in a report entitled ''Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results.'' The final report is posted on the CDER Web site at *http://www.fda.gov/cder/ddmac/researchka.htm*.

Medical device DTC promotion has not received as much FDA attention because, until recently, there had not been a significant amount of DTC device promotion except in limited areas. To date, FDA has not conducted research specifically on the effects of DTC device promotion. Because of recent increases in DTC device promotion and a growing awareness among consumers that medical devices may give them important choices, FDA wants to use this public hearing as a forum for those interested in, and affected by, DTC promotion of medical devices.

C. Implementation of Current Regulations

There are no regulations that specifically address consumer-directed promotional materials. Therefore, since 1985 FDA has applied the act and the prescription drug advertising regulations to both professional and consumer-directed promotion. Nor does the act distinguish between consumer and professional audiences in its requirement for disclosure of relevant risk information in prescription drug or restricted device advertising. Nonetheless, FDA recognizes and accounts for the differences between healthcare professionals and consumers as recipients of drug promotion, including differences in medical and pharmaceutical expertise, perception of pharmaceutical claims, and information processing. For these reasons, in its regulation of DTC promotion, FDA has tried to ensure that adequate contextual information for benefits and risks is presented and to encourage sponsors to provide such information in language understandable to consumers.

D. Pending Citizen Petitions

We note that FDA has received a number of citizen petitions that address DTC promotion. The positions advocated by these petitions vary considerably. One petition (Docket No. 1991P–0337) requests that FDA ban direct-to-consumer advertising of prescription drugs. A second petition (Docket No. 1991P–0227) 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 (Docket Nos. 1989P–0505 and 1995P–0104), updated and reissued by the petitioner, maintains that consumer-directed prescription drug advertising should not be regulated under § 202.1. It also maintains: (1) That FDA should issue new regulations to address prescription drug advertisements directed to consumers and (2) that until such time as new regulations are established, FDA should issue a policy statement and regulation stating that prescription drug advertisements directed to the general public are exempt from the advertising regulations under § 202.1. Finally, two petitions (Docket No. 1995P–0224/CP1 & CP2) reference and reiterate requests of earlier petitions to stop regulating DTC advertising under § 202.1 and also maintain that such regulations violate the First Amendment. Consistent with 21 CFR 10.30(h)(2), FDA intends to use this public hearing to further explore the issues raised in these citizen petitions and hereby incorporates the records in these citizen petition dockets into this docket.

II. Purpose and Scope of the Hearing

This hearing is intended to provide an opportunity for broad public participation and comment concerning consumer-directed promotion of regulated medical products, including human and animal prescription drugs, vaccines, blood products, and medical devices. FDA is particularly interested in hearing the views and comments from the public as to whether, and if so how, the agency's current regulations and the agency's interpretation of those regulations and actions under them should be modified to better address consumer-directed promotion of regulated products. FDA is holding this hearing because it believes the agency, the industry, and other members of the public now have enough experience with DTC promotion to understand what regulatory issues may need to be addressed in new FDA activities.

III. Issues for Discussion

Part of FDA's mission is to protect public health by helping to ensure that the promotion of medical products directed to professionals and consumers is truthful, not misleading, and contains balanced risk and benefit information. The effects of DTC promotion have been widely discussed. Proponents of DTC promotion argue that it has educational value and will improve the physician-patient relationship, increase patient compliance with drug therapy and physician visits, and generally satisfy consumer interest in obtaining desired drug information. Opponents contend that consumers do not have the expertise to accurately evaluate and comprehend prescription drug advertising; that physicians will feel pressure to prescribe drugs that are not needed; and that DTC promotion will damage the physician-patient relationship and increase drug prices.

The agency invites comment at the public hearing on the general concept of DTC promotion and its role and consequences, positive or negative; on the topics outlined in the following paragraphs; and on any aspect of DTC that is of interest to a presenter.

1. Does current DTC promotion present the benefits and risks of using medical products in an accurate, nonmisleading, balanced, and understandable way?

• *Presentation of information on benefits and the limitations of benefits*

A drug or device's approved use, or indication, is a critical piece of information for a person deciding whether to take a drug product or use a medical device. Products often have important limitations to their use, and these too need to be understood by a potential user. Some products, for example, work only in certain populations, or work with limited success; some products work only in combination with other products, or should only be used if other treatments have failed. FDA is interested in hearing whether the indications of a drug or device can be effectively communicated to a lay audience under the confines of DTC promotion and, in particular, whether the limitations of benefit can be properly communicated. FDA is also specifically interested in whether paying greater attention to the educational component of an advertisement (i.e., devoting more attention to defining the disease and its manifestations) would help consumers better understand the role drug and device therapy may play in treating that disease. More broadly, do DTC promotional ads directed at the nonmedical community need additional educational content about the disease or condition? What is the potential role of reminder ads[1] in all types of consumer promotion, such as broadcast, print, and the Internet?

One important consideration in understanding how to use prescription drugs and medical devices is the risk-benefit tradeoff. Research conducted by FDA and reported on in 2004 on patient and physician views of DTC prescription drug promotion has shown that patients and physicians believe that DTC promotion overemphasizes the benefits of prescription drugs relative to risk information. Moreover, although almost 80 percent of physicians thought that patients understood the benefits of the drug, only 30 percent of physicians believed that patients adequately understood the limitations of drug efficacy. In addition, about 60 percent of patients believed that DTC ads portray the drug as better than it really is, and about 40 percent of patients thought that the ads make it seem like the drug will work for everyone. In the 2002 patient survey, FDA found that 60 percent of patients believed that DTC ads do not provide enough risk information and, in the 2002 physician survey, 60 percent of physicians thought that patients did not understand the risks and possible negative effects of the advertised drug.[2] Despite these negative views of the adequacy of risk information, we know that risk information, as required by the regulations, is present in all compliant full-product advertisements. The agency is interested in hearing why consumers and healthcare providers may believe that risk information is not being communicated as clearly as benefit information, even though that information is present. FDA has not conducted comparable research in the area of device promotion, but part of the purpose of this meeting is to answer questions applicable to devices as well as to drugs.

Consumer audiences include a wide range of specific audiences, such as patients with fatal illnesses, the elderly or children, or caregivers. Although some DTC promotion, such as television ads, is directed to a broad audience, DTC promotion can also be targeted to a specific population. One example of such promotion is a product brochure that a healthcare professional gives to a patient along with a prescription for the product. Some consumer audiences may be more susceptible to being misled by false or misleading promotion. Should the agency take the population targeted by DTC promotion into account as it considers the regulatory framework for DTC promotion? If so, what are the additional issues that FDA should consider with respect to DTC promotion that reaches or targets specific consumer populations?

• *Presentation of risk information*

The prescription drug regulations require that advertisements present a fair balance of benefit and risk information (§ 202.1(e)(5)(ii)). They also specify that risk information be presented with a prominence and readability reasonably comparable to claims about drug benefits (§ 202.1(e)(7)(viii)). Although there are no specific regulations addressing the ''fair balance'' of device promotion, the requirements in the statute and the regulations for a ''brief statement'' of intended use and relevant risk information reflect the same concepts as those inherent in the fair balance requirement. In DTC promotion, FDA has interpreted these requirements to mean that a balanced discussion of the risks and benefits should appear in the body of the promotional material, and FDA has encouraged sponsors to provide such information in language understandable by consumers. Balancing information is intended to provide a framework for the consumer to understand and evaluate drug benefit claims in an informed manner. These disclosures also serve to facilitate and focus the physician-patient interaction. How could the content and format of risk information in promotional pieces be better communicated to consumers? Because consumers sometimes lack advanced medical knowledge, how can FDA help ensure that those consumers who are not medical experts understand a product's risks?

The specific forms of presentation in DTC prescription drug ads, particularly in television broadcast ads, may affect consumers' understanding of a product's risks. For example, the ad may continue to present positive scenes of individuals enjoying the benefits of the advertised product during the presentation of risk information, which is usually presented separately from the benefit information. Do such common advertising techniques create barriers to consumers' understanding of risk information?

• *Use of certain standard advertising strategies*

Advertising strategies typically used in nonmedical settings have raised concern when such strategies are applied to prescription drugs or restricted devices. For example, some companies offer consumers coupons, free samples, free trials, and money-back guarantees for prescription drugs in both full-product as well as reminder advertisements (which do not inform the consumer about the benefits or risks associated with the product). Are these approaches appropriate ways to influence consumers?

Another standard marketing technique uses real people, or actors portrayed as real people, to provide positive reports (testimonials) about an advertised product. Applied to medical products, this technique portrays patients who describe how a drug or device helped them manage their medical condition. In rarer instances, healthcare providers, or actors portraying them, vouch for the use of the product. Such approaches plainly do not reflect a data-oriented approach to promotion and may not be recognized by consumers as anecdotes. FDA is interested in whether and how techniques mislead consumers about the risk-benefit tradeoffs of prescription or restricted medical products.

[1] ''Reminder ads'' and ''reminder labeling'' contain the name of the drug and other limited information, but exclude all representations or suggestions about the drug(s). See 21 CFR 201.100(f), 202.1(e)(2)(i), and 801.109(d).

[2] The 2004 final report on these surveys can be found at *http://cdernet/ddmac/www-site/researchka.htm*.

• *Use of comparative DTC promotion*

Promotion that compares one product to another or to several others is becoming more common in DTC promotion. Given that this information is often scientific or numerical in nature, how can companies convey this information in a way that is informative to consumers without advanced education, and how well are companies currently doing this? One possibility is that for such promotion to be considered not misleading, it would need to provide greater than usual contextual information about how efficacy is measured; what the side effects of the various drugs, drug classes, and devices are; and whether any advantages of a drug or a device are accompanied by disadvantages.

2. Could changes in certain required prescription drug disclosures—the package insert for print ''promotional'' labeling and the brief summary for print advertisements—improve the usefulness of this information for consumers?

For prescription drugs, the act requires that labeling bear ''adequate directions for use'' of the product (21 U.S.C. 352(f)). As previously described in this document, this requirement is generally satisfied by including the entire package insert (approved product labeling) with a promotional labeling piece. However, as the package insert is written in technical language intended for healthcare professionals, its value for consumers is questionable. For promotional labeling, is the current package insert the best way to meet the requirement to bear adequate directions for use in consumer-directed materials? Are there ways to modify the content, format, and language of the package insert that would make this information more easily understood by consumers?

Advertisements that make claims about the product must 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 is known as the ''brief summary.'' This requirement is generally satisfied by reprinting the relevant sections of the package insert as the brief summary and, for this reason, its value for consumers is also questionable. As discussed in section II of this document, FDA has issued a draft guidance entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.'' The draft guidance gives several recommended alternatives to reprinting parts of the package insert as the brief summary for DTC prescription drug print advertisements. FDA is considering the comments that have been submitted to the Docket, but is interested in any additional comments on these brief summary recommendations and on other brief summary alternatives that would make the required disclosure more understandable to consumers.

FDA is currently conducting research on the content and format of the brief summary in DTC print ads for prescription drugs and will make these results available when the research is completed.

3. Could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers?

Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks (i.e., side effects, warnings, precautions, and contraindications) in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)). This is commonly referred to as the ''major statement.'' The major statement must convey the product's most important risk information and be presented as an integral part of the broadcast advertisement. It is typically presented in language that consumers can understand. Nevertheless, the major statement is a relatively brief disclosure, and many have questioned the ability of consumers to comprehend and process the information.

Broadcast advertisements are, in addition, required to present a brief summary or, alternatively, make ''adequate provision * * * for dissemination of the approved or permitted package labeling in connection with the broadcast presentation'' (§ 202.1(e)(1)). The latter is referred to as the ''adequate provision'' requirement. FDA's guidance ''Consumer-Directed Broadcast Advertisements'' describes an approach that FDA believes fulfills the adequate provision requirement for broadcast advertisements. Are there alternatives that would improve how adequate provision is made for dissemination of labeling to consumers?

The major statement, together with adequate provision for dissemination of the product's approved labeling, provides the information disclosure required for broadcast advertisements.

Is there a way to improve the usefulness of this critical information?

4. Is there a way to make information in DTC promotion of medical devices more useful to consumers?

Many of the act's requirements apply to both drug and device promotion. Hence, many of the principles used to regulate prescription drug advertising also apply to device advertising. Nevertheless, there are no regulations pertaining to restricted device advertising. FDA is committed to ensuring that consumers have accurate and nonmisleading information concerning restricted medical devices.

The act does not distinguish between broadcast and print advertising formats in its requirement for a brief statement of a restricted device's intended use and relevant risk information. There are no regulations that provide specific requirements or interpretation of the statutory requirement regarding advertising of restricted devices. Part of the agency's purpose in holding this hearing is to gather information on whether regulations governing restricted device advertising are necessary and, if so, what aspects of advertising should be addressed.

5. As new communication technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the agency consider with regard to the effect of these technologies on DTC promotion?

The current regulations were written at a time when promotion was directed toward physicians and most promotional pieces were static print displays. Not only has the target for these promotions broadened—most notably to include consumers—but the modes of dissemination have changed and continue to evolve. For several years now, DTC promotion has occurred on television and on the radio; both vehicles are quite different from standard print media. In addition, FDA research has shown great increases in the number of people who now use the Internet to search for information about prescription drugs. Drug companies produce video news releases, audio news releases, and print ''advertorials,'' which are disseminated to TV and radio stations. At times, TV and radio stations do not make it clear to consumers that such promotional pieces are generated by regulated industry. The agency is interested in hearing the public's views on these promotional techniques and the issues they raise.

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.

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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.