DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0042]

Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; Withdrawal; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three draft guidances for industry designed to improve information provided to consumers and health care practitioners by medical product firms about medical products and health conditions. The three guidances are entitled: ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements'' (Brief Summary Guidance), ''Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms'' (Disease Awareness Guidance), and ''Consumer-Directed Broadcast Advertising of Restricted Devices '' (Device Broadcast Advertising Guidance). FDA is also announcing the withdrawal of the draft guidance for industry entitled ''Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements.''

DATES: Written comments on the draft guidances may be submitted by May 10, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Lesley R. Frank, Center for Drug Evaluation and Research (HFD–42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2831.

Regarding prescription human biological products: Glenn N. Byrd, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028.

Regarding medical device products: Deborah Wolf, Center for Devices and Radiological Health (HFZ–300), 2098 Gaither Road, Rockville, MD 20850, 301–594–4589.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three draft guidances designed to improve information provided to consumers and health care practitioners by medical product firms about medical products and health conditions. The guidances were prepared in part based on discussions and presentations at an open public meeting on consumer-directed advertising that FDA held in September 2003, *http://www.fda.gov/cder/ddmac/DTCmeeting2003.html*. The three guidances are entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements'' (Brief Summary Guidance), ''Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms'' (Disease Awareness Guidance), and ''Consumer-Directed Broadcast Advertising of Restricted Devices '' (Device Broadcast Advertising Guidance). The draft guidances are intended to provide clear advice to medical product firms on the rules applicable to certain communications to consumers and health care practitioners.

One of the principal objectives of the three guidances is to encourage prescription drug firms to present risk information in their consumer-directed advertisements using language that is understandable by a lay user. Another purpose of the guidances is to encourage drug and medical device firms to disseminate truthful, nonmisleading, scientifically accurate information on medical products and health conditions to consumers and health care practitioners. The agency believes that, given clear guidelines, firms will be more likely to provide such information, and that this increased information flow will encourage consumers to seek, and health care practitioners to provide, appropriate diagnosis and treatment, particularly of under-diagnosed and under-treated conditions. The guidances are discussed in more detail in section II of this document.

This notice is also announcing the withdrawal of the draft guidance for industry entitled ''Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements,'' which was issued by FDA on April 23, 2001 (66 FR 20468), and which is being superseded by the Brief Summary Guidance.

II. The Draft Guidances

A. The Brief Summary Guidance

FDA has responsibility under the Federal Food, Drug, and Cosmetic Act (the act) for regulating advertising for prescription drugs. Section 502(n) of the act (21 U.S.C. 352(n)), requires that an advertisement for a prescription drug contain information about the risks of using the advertised product. This requirement is further defined in the prescription drug advertising regulations in part 202 (21 CFR part 202), and is known as the ''brief summary'' requirement. Currently, it is commonplace for manufacturers to comply with the brief summary requirement by presenting verbatim and in small type the entire risk-related sections of the FDA-approved professional labeling.

The agency believes that a print advertisement that discloses the most serious and the most common risks of a product is a better way of communicating risk information to patients than the current lengthy and technical brief summary. Accordingly, the Brief Summary Guidance describes how sponsors can use FDA-approved patient labeling or Highlights of the FDA-approved professional labeling to provide risk information in consumer-directed print advertisements for prescription drugs.

The guidance also encourages the use of consumer-friendly language in advertisements that use highlights of FDA-approved professional labeling (or, before the proposed rule revising the format and content requirements of professional labeling become effective, the risk information that would appear in Highlights) to present risk information. At the same time, FDA is making clear that it remains permissible under section 502(n) of the act to present the entire risk-related sections of FDA-approved professional labeling verbatim in a consumer-directed print advertisement for prescription drugs.

B. The Disease Awareness Guidance

FDA has authority under the act to regulate the ''labeling'' and ''advertising'' of prescription drugs and

restricted devices. Ordinarily, these categories include promotional messages disseminated by or on behalf of a drug or device firm recommending use of a drug or device or containing some claim of safety or effectiveness for a drug or device. One of the principal requirements for labeling and advertising is the disclosure of risk information (either the full FDA-approved professional labeling or the brief summary). The labeling and advertising rules do not apply to certain other forms of communication by or on behalf of drug and device firms. One of these categories is disease awareness communications.

The Disease Awareness Guidance is intended to eliminate any confusion as to what principles FDA will apply in determining whether communications by or on behalf of drug and device firms qualify as ''labeling''or ''advertising,'' or as disease awareness communications. FDA believes that firms are already engaged in a substantial amount of disease awareness communication aimed at consumers (so-called ''help-seeking'' communications). Manufacturers may, however, be less familiar with disease awareness communications directed at health care professionals. Accordingly, this draft guidance contains examples of materials currently distributed to health care practitioners by government entities and educational organizations about health conditions to help demonstrate to drug and device firms the kinds of disease awareness materials they might also disseminate. FDA believes that this will encourage firms to distribute disease awareness information not only to patients, but also to health care practitioners, thereby encouraging more widespread diagnosis and treatment of under-diagnosed and under-treated health conditions.

The draft guidance also addresses the important issue of when disease awareness communications become subject to FDA regulation as ''labeling'' or ''advertising'' by virtue of their presentation in combination with so-called ''reminder'' advertisements or labeling or product-claim advertisements or labeling.

C. The Device Broadcast Advertising Guidance

In 1999, FDA issued final guidance to industry on a manner in which consumer-directed broadcast advertisements for prescription drugs could satisfy statutory and regulatory requirements for the presentation of risk information. The Device Broadcast Advertising Guidance adopts the same approach for restricted devices, with minor revisions recognizing the differences in statutory provisions relating to prescription drugs and restricted devices.

III. Good Guidance Practices

These draft guidances are being issued consistent with FDA's good guidance practices (GGPs) regulations (21 CFR 10.115). They represent the agency's current thinking on certain issues relating to certain types of communications about medical products and health conditions. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Alternative approaches may be used if such approaches satisfy the requirements of the applicable statutes and regulations.

IV. Comments

FDA specifically requests comments on the following issues:

1. The Device Broadcast Advertising Guidance, like its CDER counterpart issued in 1999, does not address the meaning of ''major statement'' in §202.1(e)(1) (21 CFR 202.1(e)(1)). Should FDA issue guidance on this issue? If the agency should, what should the guidance provide?

2. The Brief Summary Guidance contemplates that firms will disclose risk information in their consumer-directed print advertisements for prescription drugs in ways that focus on the most serious and the most common risks, and explains that this includes all warnings, all contraindications, and certain precautions and adverse events. Does the draft guidance provide sufficiently concrete advice on this point? If it does not, how should the guidance be revised?

In the guidance documents themselves, FDA requests comments on the following issues:

1. In the Brief Summary Guidance, FDA requests comments, suggestions, or results of research to help the agency assess ways in which risk information can be presented to consumers (e.g., in a text box with accompanying brief summary-type disclosure, or in the main body of the advertisement without such accompanying disclosure).

2. In the Disease Awareness Guidance, FDA requests comments on whether data exist that help establish specific criteria for defining ''close physical or temporal proximity'' to use in evaluating whether bookend-type communications are within FDA's ''labeling'' or ''advertising'' authority under the act.

Interested persons may submit written or electronic comments on the draft guidances to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments should identify clearly which guidance they are commenting on. The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines*, or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: February 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0277]

Draft Guidance for Industry on Time and Extent Applications; 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 ''Time and Extent Applications.'' This guidance is being written to assist those persons interested in adding a new condition to the over-the-counter (OTC) drug monograph system. A time and extent application (TEA) can be submitted for FDA to determine whether a condition is eligible to be considered for inclusion in an OTC drug monograph. This guidance is designed to clarify issues concerning the TEA in an effort to facilitate the application process.

DATES: Submit written or electronic comments on the draft guidance by April 12, 2004. 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,