Guidance for Industry

Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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DDMAC

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides recommendations on the disclosure of risk information in prescription drug product advertisements directed toward consumers in print media. This draft guidance supersedes the draft guidance on *Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements*, which was issued in April 2001. This guidance does not focus on the presentation of risk information in the main body of the advertisement.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required. Thus, FDA does not intend to object to a consumer-directed print advertisement on the ground that it does not fulfill the brief summary requirement solely because it does not comply with the recommendations set forth in this guidance document. Although FDA cannot object to a consumer-directed print advertisement for a prescription drug solely on the basis that the risk information is not presented in consumer-friendly language, the Agency strongly encourages the use of consumer-friendly language in all consumer-directed materials, for the reasons discussed in section III of this document.

[1] This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER) in coordination with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

II. BACKGROUND

Under the Federal Food, Drug, and Cosmetic Act (the Act), FDA is responsible for regulating the advertising of prescription drugs. Under Section 502(n) of the Act (21 U.S.C. 352(n)), an advertisement for a prescription drug must contain, in addition to the product's established name and quantitative composition, a "true statement" including "information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations . . . ." This requirement is further defined in the prescription drug advertising regulation at 21 CFR 202.1(e)(1), which requires that an advertisement contain a "true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness." Under 21 CFR 202.1(e)(3)(iii)): "The information relating to side effects and contraindications shall disclose *each specific side effect and contraindication* (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc. . . .) contained in required, approved, or permitted labeling for the advertised drug dosage form(s)" (emphasis added). For purposes of this guidance, the requirement under these provisions that an advertisement for a prescription drug disclose each side effect, warning, precaution, and contraindication from the required, approved, or permitted labeling is *the brief summary requirement*.

Frequently, to fulfill the brief summary requirement, consumer-directed print advertisements for prescription drugs include the complete risk-related sections of the FDA-approved professional labeling. This information is presented verbatim, in small type. Because this labeling is written for an audience of health care practitioners, it uses highly technical medical terminology. In addition, although the Agency has drafted guidance discouraging this practice,[2] FDA-approved professional labeling has often included all possible adverse events, including those that are unlikely to be drug related.

Although this approach complies with the brief summary requirement, FDA believes it is less than optimal for consumer-directed print advertisements because many consumers do not have the technical background to understand this information. Moreover, the volume of the material, coupled with the format in which it is presented (i.e., very small print and sophisticated medical terminology) discourages its use and makes the information less comprehensible to consumers. In general, FDA believes that exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks. FDA also believes that information intended for a consumer should optimally be communicated in language fully understandable by a lay reader and presented in an easily readable format.

In 2000, FDA proposed amending its regulations on the format and content of FDA-approved professional labeling for human prescription drug and biological products (proposed rule).[3] Under the proposed rule, FDA-approved professional labeling would contain a new introduction

[2] See Guidance for Industry, Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics (DRAFT) (May 2000).

[3] Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirement for Prescription Drug Product Labels (65 FR 81082, December 22, 2000).

section called Highlights of Prescribing Information (Highlights). Highlights would set forth in a concise manner the information that is most important to safe and effective use, including information on the most common and the most serious risks associated with the product.

If the proposed rule were to become effective, then the FDA-approved professional labeling for new and recently approved drugs and labeling approved by FDA according to supplemental premarket approval applications would include Highlights that FDA believes would be appropriate for manufacturers to use when presenting risk information in consumer-directed print advertisements for prescription drugs. Ideally, the Highlights would be translated from language appropriate for a professional audience into language easily understood by the average consumer. This option is discussed in greater detail in section III.B of this guidance document. Alternatively, a manufacturer could present risk information in its consumer-directed print advertisements by: (1) presenting all risk information from the FDA-approved professional labeling; or (2) reproducing FDA-approved patient labeling, either in its entirety or as modified to omit less important risk information (see section III.A).

Unless and until the proposed rule goes into effect, a manufacturer can (1) present all risk information from the FDA-approved professional labeling; (2) reproduce FDA-approved patient labeling, either in its entirety or as modified to omit less important risk information (see section III.A); or (3) provide the risk information that would be appropriate for FDA-approved Highlights (see section III.B).

On April 23, 2001, FDA announced in the *Federal Register* (66 FR 20468) the availability of a draft guidance for industry entitled *Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements*. The draft guidance described how certain FDA-approved patient labeling could be used to disclose risk information in consumer-directed print advertisements for prescription drugs. This draft guidance differs from the previous draft guidance in that it describes several options for disclosing risk information in consumer-directed print advertisements. And, as noted above, this draft guidance supersedes the earlier one.

III. OPTIONS FOR DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS

In the circumstances described below, FDA does not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information in compliance with the brief summary requirement. Each of the following approaches would provide information on the most serious and the most common risks associated with the product, and would omit less important information.

FDA recommends that any advertisement disseminated as described below include a statement reminding consumers that the information presented is not comprehensive and providing a toll-free telephone number or Web site address (URL) where consumers can obtain additional information if they wish.

A. FDA-Approved Patient Labeling

A prescription drug may have, in addition to FDA-approved professional labeling, *FDA-approved patient labeling*. This labeling can include Information for the Patient, a Medication Guide, Patient Information, or a Patient Package Insert. Although less extensive than the FDA-approved professional labeling, FDA-approved patient labeling provides risk and benefit information that is material to the decision by the patient (with the involvement of a health care practitioner) whether to use a prescription drug and material to safe and effective use of the drug.

Generally, FDA-approved patient labeling does not address ***each*** specific risk included in the FDA-approved professional labeling. Instead, FDA-approved patient labeling communicates the most important information patients need to use the product appropriately, and it focuses on the product's most serious risks and its less serious, but most frequently occurring, adverse reactions. We believe that omitting less serious, infrequent risks from patient labeling may actually increase the usefulness of this labeling for its audience by making the more important risks stand out more clearly. For these reasons, FDA believes that FDA-approved patient labeling is a better vehicle for communicating risk information to consumers than lengthy, technical FDA-approved professional labeling.

Not all FDA-approved patient labeling describes a product's most serious risks and its less serious, but most frequently occurring, adverse reactions. Some FDA-approved patient labeling primarily gives instructions for use (e.g., directions on how to use medications delivered through inhalation, a patch, or injection). Other FDA-approved patient labeling focuses primarily on a single important warning. Where FDA-approved patient labeling has a narrow focus and does not provide information on the product's most serious risks and its less serious, but most frequently occurring, adverse reactions, FDA believes this labeling would not be suitable for conveying risk information in a consumer-directed print advertisement.

The Agency recognizes that some FDA-approved patient labeling includes information in addition to risk information (e.g., directions for use or a discussion of the disease state being treated). Deletion of this information from the labeling when using it to present risk information in a consumer-directed print advertisement is likely to help the consumer focus on the most important risk information for the drug.

The following describes the Agency's thinking on the use of FDA-approved patient labeling to present risk information in consumer-directed print advertisements for prescription drugs instead of presenting verbatim the risk-related sections of FDA-approved professional labeling.

1. Reprinted as Approved

FDA does not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information in compliance with the brief summary requirement if it includes the FDA-approved patient labeling for

the drug and if that labeling: (1) is reprinted in full in the advertisement; and (2) includes information from the advertised product's FDA-approved professional labeling addressing the following risks:

- Contraindications: all;
- Warnings: all;
- Precautions: the major precautions, including any that describe serious adverse drug experiences (as defined in 21 CFR 312.32(a) & 314.80(a)) or steps to be taken to avoid such experiences; and
- Adverse Reactions: the 3-5 most common nonserious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy.

Infrequently, risk information included in the Precautions or Adverse Reactions section of FDA-approved professional labeling would, under current practice, appear in the Warnings section. In such a case, that risk information should be deemed to appear in the Warnings section for purposes of this guidance document.

2. Reprinted Risk Information Only

FDA does not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information in compliance with the brief summary requirement if it includes the FDA-approved patient labeling for the drug and if that labeling: (1) has been modified to include only risk information (e.g., by deleting instructions for use); and (2) includes information from the advertised product's FDA-approved professional labeling addressing the following risks:

- Contraindications: all;
- Warnings: all;
- Precautions: the major precautions, including any that describe serious adverse drug experiences (as defined in 21 CFR 312.32(a) & 314.80(a)) or steps to be taken to avoid such experiences; and
- Adverse Reactions: the 3-5 most common nonserious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy.

Infrequently, risk information included in the Precautions or Adverse Reactions section of FDA-approved professional labeling would, under current practice, appear in the Warnings section. In such a case, that risk information should be deemed to appear in the Warnings section for purposes of this guidance document.

B. Highlights

1. Before the Proposed Rule Becomes Effective

Unless and until the proposed rule becomes effective, FDA does not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does

not present risk information in compliance with the brief summary requirement if it includes the risk information that would appear in the Highlights section of FDA-approved labeling for the product, including information addressing the following risks:

- Contraindications: all;
- Warnings: all;
- Precautions: the major precautions, including any that describe serious adverse drug experiences (as defined in 21 CFR 312.32(a) & 314.80(a)) or steps to be taken to avoid such experiences; and
- Adverse Reactions: the 3-5 most common nonserious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy.

Infrequently, risk information included in the Precautions or Adverse Reactions section of FDA-approved professional labeling would, under current practice, appear in the Warnings section. In such a case, that risk information should be deemed to appear in the Warnings section for purposes of this guidance document.

2. If the Proposed Rule Were to Become Effective

If the proposed rule were to go into effect, FDA would not intend to object to a consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information in compliance with the brief summary requirement if the advertisement reproduces the parts of the Highlights of FDA-approved professional labeling that set forth risk information (e.g., Boxed Warning, Contraindications, Warnings/Precautions, Most Common Adverse Reactions).

To illustrate, we are providing as separate documents (1) an example of a fictional prescription drug product Highlights and (2) an example of the fictional Highlights in consumer-friendly format and language illustrating an appropriate way to convey risk information under this option. The example omits some non-risk information, such as How Supplied and Dosage and Administration information.

3. FDA Recommendations On Use Of Consumer-Friendly Language

For consumers to realize full benefit from the more streamlined presentation of risk information described in section IV.B.1 and 2, Highlights ideally should be written in language fully understandable by a lay reader and should not contain technical, scientific terms or jargon. Thus, FDA encourages Highlights intended for use in consumer-directed print advertisements to be written in language that is easy to understand, use, or deal with by ordinary individuals under normal conditions. For example, a consumer may not understand the term “Contraindications” but is more likely to understand the phrase “You should not take drug X if . . . .”

IV. REQUEST FOR THE VIEWS OF INTERESTED PARTIES

In this draft guidance, FDA describes several options for presenting the risk information in consumer-directed print advertisements. In crafting these options, FDA evaluated several approaches for communicating complex information in various labeling formats. Examples of the agency's past experience in this area include both the redesign of food labeling under the Nutritional Labeling and Education Act of 1990[4] and the standardization of the format and content for the labeling of over-the-counter drug products.[5]

The promotion of prescription drugs differs from the promotion of many other products. While prescription drugs offer medical benefits, these products may also pose significant risks to patients. Based on available data and information, and on the results of FDA's own research, the agency believes consumer-directed promotion of prescription drugs can convey useful health information to patients. But for such promotion to have this beneficial effect, it must be truthful, non-misleading, and scientifically substantiated. This means, for example, that prescription drug promotion must include appropriate information on the risks associated with the use of the drug, and that this information must be properly presented.

FDA recognizes that the language and format chosen to present risk information can affect consumer understanding. We have not evaluated how presenting the information in different formats affects consumer comprehension, and we believe that there is much to be learned before we develop final guidance on how best to inform patients about the drugs being promoted. Therefore, the agency is soliciting comments, suggestions, or results of research in this area from interested parties to help assess what is most useful for consumers to ensure that they are provided with concise, understandable risk information that will help them make well-informed decisions. The agency is also encouraging the development of new approaches to presenting risk information.

For example, as noted above, risk information in a consumer-directed print advertisement for a prescription drug is set forth in detail in an accompanying "brief summary" and is also incorporated into the text in the body of the advertisement. An alternative to including risk information in the text in the body of the advertisement would be to include risk information as bullet points in a "risk information window" in the body of the advertisement. The window could appear prominently in the advertisement (e.g., in the top half) and could bear a title (e.g., "Important Safety Information") calling attention to the information it contains. FDA specifically requests comments on this approach. A specific issue on which FDA requests comment is whether, in some cases, it may be impossible for all of the necessary risk information to be presented in a bullet format in the risk information window. FDA requests comments on whether, in those cases, FDA should recommend that the bulleted information be accompanied by additional risk information in the text in the body of the advertisement.

[4] Pub. L. No. 101-535 (Nov. 8, 1990).

[5] See, e.g., 64 FR 13254; March 17, 1999.

297 Some have suggested that the essence of the risk information could be incorporated into the body
298 of the advertisement, obviating the need for disclosure of risk information in a separate part of
299 the advertisement. FDA requests comments on such an approach, including on whether this
300 approach might be appropriate for only a subset of prescription drugs (e.g., drugs with safety
301 profiles that can be succinctly summarized).