

---

# Guidance for Industry

## Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements

### *DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Nancy M. Ostrove at 301-827-2828, or (CBER) Toni Stifano at 301-827-6190.

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)  
April 2001

DDMAC

*Draft - Not for Implementation*

# Guidance for Industry

## Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements

*Additional copies are available from:*

*Office of Training and Communications  
Division of Communications Management  
Drug Information Branch, HFD-210  
5600 Fishers Lane  
Rockville, MD 20857  
(Tel) 301-827-4573*

*(Internet) <http://www.fda.gov/cder/guidance/index.htm>*

*or*

*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  
Internet: <http://www.fda.gov/cber/guidelines.htm>  
Fax: 1-888-CBERFAX or 301-827-3844*

*Phone: the Voice Information System at 800-835-4709 or 301-827-1800*

**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)**

**April 2001**

**DDMAC**

***Draft - Not for Implementation***

**Table of Contents**

**I INTRODUCTION..... 1**

**II BACKGROUND..... 1**

**III FULFILLING THE BRIEF SUMMARY REQUIREMENT..... 3**

**GUIDANCE FOR INDUSTRY<sup>1</sup>**

**Using FDA-Approved Patient Labeling in Consumer-Directed  
Print Advertisements**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**I. INTRODUCTION**

This guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure. FDA-approved patient labeling is also called *Information for the Patient*, *Patient Information*, *Medication Guide*, and *patient package inserts*.

**II. BACKGROUND**

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the act) requires that advertisements for prescription drugs and biological products include a true statement of information in brief summary relating to side effects, contraindications, and effectiveness (i.e., information about the benefits and risks of using the advertised product). This is also known as the *brief summary* requirement. Generally, the display text of an advertisement discloses the product's indication and benefits. The prescription drug advertising regulations (21 CFR 202.1(e)(3)(iii)) specify that the information about risks must include *each specific side effect and contraindication* from the advertised drug's approved labeling. The regulation also specifies that the phrase *side effect and contraindication* refers to all of the categories of risk information required in the approved product labeling

---

<sup>1</sup>This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

## **Draft - Not for Implementation**

40 written for health professionals, including the Warnings, Precautions, and Adverse  
41 Reactions sections. Thus, every risk in an advertised drug's approved labeling must be  
42 addressed to meet these regulations.

43  
44 Because the regulations do not specify how to address each risk, sponsors can use  
45 discretion in fulfilling the brief summary requirement under 202.1(e)(3)(iii). Frequently,  
46 sponsors print in small type, verbatim, the risk-related sections of the approved product  
47 labeling (also called the package insert, professional labeling, prescribing information, and  
48 direction circular). This labeling is written for health professionals, using medical  
49 terminology. FDA believes that this is one reasonable way to fulfill the brief summary  
50 requirement for print advertisements directed toward health professionals, but may be  
51 difficult for consumers to understand.

52  
53 In addition to professional labeling, some prescription drugs and biological products have  
54 FDA-approved labeling written for patients using the product. Such labeling generally  
55 contains information describing the product's risks and benefits, although some labeling  
56 describes the risks more fully than others. Generally, patient labeling does not fulfill the  
57 brief summary requirement because it does not always address "each specific" risk  
58 included in the labeling written for health professionals. Patient labeling is designed to  
59 communicate in understandable language the most important information patients need to  
60 use the product appropriately. Therefore, patient labeling focuses on the product's more  
61 serious risks and its less serious, but frequently occurring risks. Omitting less serious  
62 infrequent risks as well as those risks not likely to be caused by the product, may actually  
63 increase the usefulness of this labeling for its audience by making the more important risks  
64 clearer.

65  
66 The Agency believes that approved patient labeling that comprehensively addresses the  
67 product's most serious and most common risks is a suitable means of communicating risk  
68 information to patients. Therefore, FDA does not intend to object to the use of this labeling,  
69 reprinted exactly as approved, to fulfill the requirement that DTC print advertisements  
70 contain a *brief summary* of the product's risks.<sup>2</sup> Such labeling generally addresses the  
71 rationale behind the law's brief summary requirement by providing benefit and risk  
72 information in a form understandable to consumers. This labeling contains the information  
73 patients are likely to find helpful in deciding whether to discuss with their health care  
74 provider the possible usefulness of the product for them. Omission of less serious  
75 infrequent events and events not likely to be drug related would not be expected to have a  
76 major effect on a patient's decision to discuss a drug with a doctor. Patients desiring more  
77 complete information can obtain it from their health care provider or by referring to labeling  
78 that is written for health care providers.

79

---

<sup>2</sup> This guidance does not address the use of other patient-directed prescription drug information as a brief summary for a DTC print advertisement. If a sponsor wants to use information other than the approved patient labeling, the summary would have to include *all* the risk information required by 21 CFR 202.1(e)(3)(iii).

## ***Draft - Not for Implementation***

80 FDA intends to object to the use of approved patient labeling as a brief summary for DTC  
81 print advertisements if the labeling *does not* comprehensively address the product's most  
82 serious and most common risks.

83  
84

### **III. FULFILLING THE BRIEF SUMMARY REQUIREMENT**

86

87 FDA does not intend to object to the use of FDA-approved patient labeling to fulfill the brief  
88 summary requirement for DTC print advertisements if the labeling is reprinted in full and  
89 discusses in consumer-friendly language the following information from the advertised  
90 product's approved physician labeling:

91

- 92 • All the contraindications
- 93 • All the warnings
- 94 • All the major precautions
- 95 • All other frequently occurring side effects that are likely to be drug-related

96

97 Information from the product's approved physician labeling that need not be addressed in  
98 the FDA-approved patient labeling includes:

99

- 100 • Side effects that are not serious and do not occur frequently or that are unlikely to be  
101 the result of taking the product
- 102
- 103 • Information related to carcinogenesis, mutagenesis, and infertility that does not  
104 warrant a discussion under the Warnings section
- 105
- 106 • Information related to use in pregnancy that does not warrant a *D* or *X* pregnancy  
107 category
- 108
- 109 • Information related to use in labor and delivery, breast-feeding, pediatrics, and other  
110 special populations that does not warrant a discussion under the Warnings section

111

112 Some examples of products with FDA-approved patient labeling that FDA would not object  
113 to for use as a brief summary for DTC print advertisements include:

114

- 115 • Evista
- 116 • Fosamax
- 117 • Glucophage
- 118 • Singulair
- 119 • Tikosyn
- 120 • Xenical
- 121 • Ziagen

122

123 Some FDA-approved patient labeling focuses primarily on giving instructions for use.  
124 Other FDA-approved patient labeling focuses on a single warning. Neither of these types

***Draft - Not for Implementation***

125 of patient labeling provides the comprehensive important risk information that addresses  
126 the rationale behind the brief summary requirement. Because of the narrow focus of such  
127 labeling, FDA intends to object to its use as a brief summary for DTC print advertisements.

128 Examples of such FDA-approved patient labeling include:

129

- 130 • ACE Inhibitors
- 131 • Isoproterenol inhalers