Guidance for Industry: Consumer-Directed Broadcast Advertisements

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Guidance for Industry

Consumer-Directed Broadcast Advertisements

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)
Center for Veterinary Medicine (CVM)
August 1999

DDMAC

Guidance for Industry

Consumer-Directed Broadcast Advertisements

Additional copies of this Guidance are available from:

Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857
(Phone 301-827-4573)
Internet: http://www.fda.gov/cder/guidance/index.htm.

or

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Fax: 1-888-CBERFAX or 301-827-3844
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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)
Center for Veterinary Medicine (CVM)
August 1999

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GUIDANCE FOR INDUSTRY[1]

Consumer-Directed Broadcast Advertisements

I. INTRODUCTION

This guidance is intended to assist sponsors who are interested in advertising their prescription human and animal drugs, including biological products for humans, directly to consumers through broadcast media, such as television, radio, or telephone communications systems.[2]

II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, the Act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness" (21 U.S.C. 352(n)). The resulting information disclosure is commonly called the *brief summary*.

The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Print advertisements must include the brief summary, which generally contains each of the risk concepts from the product's approved package labeling. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the *major statement*. This guidance does not address the major statement requirement.

Sponsors of broadcast advertisements are also required to present a brief summary or, alternatively, may make "adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (21 CFR 202.1(e)(1)). This is referred to as the *adequate provision* requirement. The regulations thus specify that the major

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[1] This guidance has been prepared by the Intra-Agency Group on Advertising and Promotion at the Food and Drug Administration. This guidance represents the Agency's current thinking on procedures to fulfill the requirements for disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human and animal drugs, and human biological products. 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 statute, regulations, or both.

[2] This guidance is not intended to cover the advertising of restricted medical devices, which are subject to the requirements of section 502(r) of the Federal Food, Drug, and Cosmetic Act.

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

The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for *adequate provision* in connection with consumer-directed broadcast advertisements for prescription drug and biological products. The approach presumes that such advertisements:

- Are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.

- Present a fair balance between information about effectiveness and information about risk.

- Include a thorough *major statement* conveying all of the product's most important risk information in consumer-friendly language.

- Communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.

III. FULFILLING THE *ADEQUATE PROVISION* REQUIREMENT

A sponsor wishing to use consumer-directed broadcast advertisements may meet the adequate provision requirement through an approach that will allow most of a potentially diverse audience to have reasonably convenient access to the advertised product's approved labeling. This audience will include many persons with limited access to technologically sophisticated outlets (e.g., the Internet) and persons who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. One acceptable approach to disseminating the product's approved labeling is described below. This approach includes the following components.

A. Disclosure in the advertisement of an operating toll-free telephone number for consumers to call for the approved package labeling. Upon calling, consumers should be given the choice of:

- Having the labeling mailed to them in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days); or

- Having the labeling read to them over the phone (e.g., by offering consumers a selection of prerecorded labeling topics).

B. Reference in the advertisement to a mechanism to provide package labeling to

consumers with restricted access to sophisticated technology, such as the Internet, and those who are uncomfortable actively requesting additional product information or are concerned about being personally identified in their search for product information. One acceptable mechanism would be to provide the additional product information in the form of print advertisements appearing concurrently in publications that reach the exposed audience. The location of at least one of these advertisements would be referenced in the broadcast advertisement. If a print advertisement is part of an adequate provision procedure, it should supply a toll-free telephone number and an address for further consumer access to full package labeling. This mechanism of providing access to product labeling has the advantage of also providing considerable information in the form of the required brief summary and in the advertising text itself.

When a broadcast advertisement is broadly disseminated, FDA believes that ensuring that passive and privacy-sensitive information seekers have adequate access to detailed product information is critical to complying with the *adequate provision* regulatory requirement. Thus, print advertisements associated with broadly disseminated broadcast advertisements should be comparably broadly disseminated in terms of the targeted audiences.

An alternative mechanism for providing private access to product information would be to ensure the availability of sufficient numbers of brochures containing package labeling in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries). Brochures should be available at enough sites so that most consumers exposed to the broadcast advertisement can obtain the labeling without traveling beyond their normal range of activities. This alternative mechanism is likely to be logistically feasible only when the associated broadcast advertising campaign is relatively limited in audience reach.

C. Disclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling.

D. Disclosure in the advertisement that pharmacists, physicians (or other healthcare providers), or veterinarians (in the case of animal drugs) may provide additional product information to consumers. This statement should communicate clearly that the referenced professional is a source of additional product information.

Telephone advertisements that make a product claim (not reminder advertisements) occur when there is a telephone communication between an individual and a product's sponsor where both a product name and a representation or suggestion relating to a product (e.g., its indication) are disclosed by the sponsor. Under these circumstances, such advertisements are subject to the disclosure requirements of the Act and the regulations. However, telephone advertisements are different from advertisements broadcast through television and radio. By participating in the telephone communication, the consumer has already indicated his or her willingness to discuss the topic or receive additional information. Consequently, adequate provision for disseminating product labeling in connection with telephone advertisements may be achieved with fewer of the

components listed above. For such advertisements, adequate provision could consist of the availability of the option of having product labeling mailed to the caller in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days), or having the labeling read to them over the phone (e.g., by allowing consumers to select from prerecorded labeling topics), as well as disclosing that healthcare providers are a source of additional product information.

When a broadcast advertisement is presented in a foreign language, the information sources that are part of the advertisement's "adequate provision" mechanism (i.e., print advertisements or brochures, web sites, toll-free telephone number recorded messages or operators) should be in the language of the broadcast ad. Regardless of the language used for the advertisement, current broadcast advertising regulations require the dissemination of approved product labeling, which, in most cases, must be in English, and is generally written in language directed to healthcare professionals. The Agency strongly encourages sponsors to consider the benefits of ***also*** providing consumers with nonpromotional, consumer-friendly product information in the language of the broadcast ad (e.g., FDA-approved patient labeling or accurate, consumer-friendly translations of product labeling information).

The FDA encourages sponsors who use this *adequate provision* mechanism to collect relevant data on consumer use and make their findings publicly known. FDA also encourages sponsors and other interested parties to make known their research relating to the overall effects of DTC promotion on the public health.

Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials

Final guidances and draft guidances published for comment are posted on the internet at www.fda.gov/cder/guidance.

Guidance for Industry

Accelerated Approval Products — Submission of Promotional Materials

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 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 on the content of the draft document contact (CDER) Tracy L. Acker, 301-827-2831 or (CBER) Toni M. Stifano, 301- 827-3028.

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)
March 1999
DDMAC #

Draft - Not for Implementation

Guidance for Industry

Accelerated Approval Products — Submission of Promotional Materials

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Center for Drug Evaluation and Research (CDER)
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March 1999
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TABLE OF CONTENTS

Draft - Not for Implementation

GUIDANCE FOR INDUSTRY[1]

Accelerated Approval Products — Submission of Promotional Materials

I. INTRODUCTION

This guidance is intended to describe procedures that sponsors of human prescription drug and biological products can use to submit promotional materials to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) under 21 CFR 314.550 and 601.45 for products approved under the accelerated approval regulations[2].

In the context of this draft guidance, the term *promotional materials* includes promotional labeling and advertisements. Examples of labeling include, but are not limited to, brochures, booklets, detailing pieces, bulletins, calendars, motion pictures, and slides (21 CFR 202.1(l)(2)). Advertisements include, but are not limited to, materials published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems (§ 202.1(l)(1)).

II. BACKGROUND

In the *Federal Register* of December 11, 1992 (57 FR 58942), FDA published final regulations under which the Agency would accelerate the approval of certain new drugs and biological products for serious or life-threatening illnesses. The accelerated approval regulations require that, unless otherwise informed by the Agency, applicants submit to FDA copies of all promotional materials, including promotional labeling and advertisements, intended for

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[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 consultation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on the process for submitting promotional materials for accelerated approval products. 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 statute, regulations, or both.

[2] Sponsors whose drug or biological product is in a fast track program that is eligible for approval under section 506(b) of the Federal Food, Drug, and Cosmetic Act are also subject to 314.550 and 601.45 and can use these procedures.

dissemination or publication within the first 120 days following marketing approval during the ***preapproval review period*** (see 21 CFR 314.550 and 601.45). The regulations require further that promotional materials intended for dissemination any time after the 120-day postapproval period be submitted at least 30 days prior to the intended date of initial dissemination or publication of those materials, unless otherwise informed by the Agency.

III. COMMUNICATING WITH FDA DURING THE PREAPPROVAL REVIEW PERIOD

To the extent that a sponsor anticipates approval of a product under the accelerated approval provisions, FDA encourages sponsors to begin communication with the appropriate division early in the application review process regarding submission of draft promotional materials for review during the preapproval period. Sponsors should contact CDER, Division of Drug Marketing, Advertising, and Communications (DDMAC) or CBER, Advertising and Promotional Labeling Staff (APLS), Office of Compliance and Biologics Quality. Early communication with DDMAC or APLS should enable the sponsor to understand and comply with the submission requirements prior to product approval or licensing.

IV. PROMOTIONAL MATERIALS INTENDED FOR USE DURING THE 120-DAY POSTMARKETING PERIOD

A. General Requirements for Submission and Review

As previously noted, unless otherwise informed by FDA, applicants must submit to the Agency copies of all promotional materials, including promotional labeling and advertisements, intended for dissemination or publication within 120 days following marketing approval ***prior to*** approval or licensing (21 CFR 314.550 and 601.45). FDA's goal is to provide comments in a timely manner, usually within 15 working days of the day the materials are received by DDMAC or APLS. The Agency expects that materials will ***not*** be disseminated or published until the Agency's objections are resolved. FDA recommends that the applicant plan sufficient time for resolving differences with the Agency concerning the submitted materials prior to dissemination or publication.

In some cases, the sponsor may respond to the Agency's comments on previously submitted materials ***after*** product approval. However, FDA expects that no promotional materials will be disseminated until the Agency's concerns have been resolved.

To the extent that product labeling is not yet final, a sponsor may be unable to provide FDA with final promotional materials prior to product approval. In such instances, the

Agency may be able to comment on many of the important aspects of the promotion based upon draft promotional materials.

B. Submissions During the 120 Day Post Approval Period

FDA expects that all promotional materials intended for use during the 120-day postapproval period will be submitted ***prior*** to product approval. However, FDA recognizes that, on rare occasions, the following circumstances may preclude a sponsor from submitting every promotional item intended for use during the 120 day postapproval period prior to approval:

i. The designation of accelerated approval status occurs late in the preapproval review period or extensive and substantive changes to draft labeling occur so late that completely new promotional materials need to be developed. Under such circumstances, the sponsor should still submit as many materials as possible ***before*** approval.

ii. A sponsor may need to address unforeseen problems or report information in labeling material that is beneficial to fostering the safe and effective use of the product after it has entered the marketplace. For example, a sponsor may have to address an unforeseen problem with product administration or availability, or an unexpectedly high incidence of an adverse event. Sponsors can request that FDA review such additional materials and should provide a rationale for distribution of these materials prior to submission of the actual materials. FDA will respond to such requests in a timely manner and, when appropriate, will provide comments on the materials.

V. PROMOTIONAL MATERIALS INTENDED FOR USE FOLLOWING THE 120-DAY POSTAPPROVAL PERIOD

Promotional materials intended for use following the 120 day postapproval period must be submitted to FDA for review at least 30 days prior to its intended dissemination or publication date, unless otherwise informed by the Agency (21 CFR 314.550 and 601.45). FDA requests that sponsors consider batching these submissions, rather than submitting multiple individual pieces. Batching will facilitate a more expeditious review. Sponsors may submit such materials for review as early as 90 days post approval (30 days prior to intended dissemination or publication). However, such materials should not be used until the Agency's concerns are resolved and until the 120 day postapproval period has expired.

Submissions should be made under cover of a letter to DDMAC or APLS requesting comments on *draft materials,* referencing the materials are being submitted pursuant to 21 CFR 314.550 or 601.45, and should include copies of draft materials and all supporting references necessary for FDA review.

FDA intends to provide the sponsor with comments as soon as possible. If the Agency notifies the sponsor of significant objections to the proposed materials, the Agency expects that these materials will not be disseminated or published until the Agency's concerns have been resolved.

Sponsors often develop promotional materials that are derivative of previously reviewed materials (i.e., materials that present product claims and representations of the same content and context as previously reviewed materials) for use after the 120-day postapproval period. These materials should also be submitted for review prior to use. FDA intends to review and comment on derivative materials in a timely manner, usually within 15 working days of the day the materials are received by FDA.

At the time of initial dissemination or publication, sponsors are required to submit final materials for drug products under cover of FDA Form 2253, pursuant to 21 CFR 314.81(b)(3)(i) and for biological products under cover of FDA Form 2567 or equivalent pursuant to 21 CFR 601.12(f)(4).

VI. TERMINATING SUBMISSION REQUIREMENTS

Under 21 CFR 314.560 and 601.46, FDA may determine after approval that the requirements established in §§ 314.550 and 601.45 are no longer necessary for the safe and effective use of a drug or biological product. If this happens, the Agency will notify the applicant in writing that advanced submission of promotional materials is no longer required. For human prescription drugs, the applicant will be notified by DDMAC in CDER. For biological products, the applicant will be notified by APLS in CBER.

DRUG ADVERTISING

Regulations covering advertising for prescription drugs and drugs approved under the regulations for accelerated approval.

[Code of Federal Regulations]
[Title 21, Volume 4, Parts 200 to 299]
[Revised as of April 1, 1999]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR200.7]

[Page 6]

TITLE 21--FOOD AND DRUGS

PART 200--GENERAL--Table of Contents

Subpart A--General Provisions

Sec. 200.7 Supplying pharmacists with indications and dosage information.

There are presently no regulations under the Federal Food, Drug, and Cosmetic Act that prevent a manufacturer of prescription drugs from sending the pharmacist data he needs on indications and dosage in exercising his important professional function of checking against possible mistakes in a prescription. The Food and Drug Administration believes manufacturers should be encouraged to supply such printed matter to the pharmacist for his professional information. Obviously, such printed matter should not be displayed to prospective purchasers to promote over-the-counter sale of prescription drugs.

[Code of Federal Regulations]
[Title 21, Volume 4, Parts 200 to 299]
[Revised as of April 1, 1999]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR200.200]

[Page 7-8]

TITLE 21--FOOD AND DRUGS

PART 200--GENERAL--Table of Contents

Subpart E--Prescription Drug Consumer Price Listing

Sec. 200.200 Prescription drugs; reminder advertisements and reminder labeling to

(a) Prescription drug reminder advertisements and reminder labeling intended to provide price information to consumers are exempt from the requirements of Secs. 201 .100 and 202.1 of this chapter if all of the following conditions are met:

(1) The only purpose of the reminder advertisement or reminder labeling is to provide consumers with information concerning the price charged for a prescription for a particular drug product, and the reminder advertisement or reminder labeling contains no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use.

(2) The reminder advertisement or reminder labeling contains the proprietary name of the drug product, if any; the established (generic) name of the drug product, if any; the drug product's strength if the product contains a single active ingredient or if the product contains more than one active ingredient and a relevant strength can be associated with the product without indicating each active ingredient (the established name and quantity of each active ingredient are not required); the dosage form; and the price charged for a prescription for a specific quantity of the drug product.

(3) The reminder advertisement or reminder labeling may also include other written, printed, or graphic matter,

[[Page 8]]

e.g., identification of professional or convenience services provided by the pharmacy: Provided, That such information is neither false nor misleading and contains no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use.

(4) The price stated in the reminder advertisement or reminder labeling as that charged for a prescription shall include all charges to the consumer including, but not limited to, the cost of the drug product, professional fees, and handling fees, if any. Mailing fees and delivery fees, if any, may be stated separately and without repetition.

(b) This exemption from Secs. 201.100 and 202.1 of this chapter is applicable to all prescription drug reminder labeling and reminder advertisements solely intended to provide consumers with information regarding the price charged for prescriptions including price lists, catalogs, and other promotional material, whether mailed, posted in a pharmacy, placed in a newspaper, or aired on radio or television.

(c) Any reminder advertisement or reminder labeling intended to provide consumers with prescription price information which is not in compliance with this section shall be the subject of appropriate regulatory action. Such action may be taken against the product and/or the responsible person.

[40 FR 58799, Dec. 18, 1975]

[Code of Federal Regulations]
[Title 21, Volume 4, Parts 200 to 299]
[Revised as of April 1, 1999]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR202.1**]

[Page 74-83]

TITLE 21--FOOD AND DRUGS

PART 202--PRESCRIPTION DRUG ADVERTISING--Table of Contents

Sec. 202.1 Prescription-drug advertisements.

(a)(1) The ingredient information required by section 502(n) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names.

(2) The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product.

(3) The advertisement shall not employ a fanciful proprietary name for the drug or any ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The advertisement shall not feature inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) The advertisement shall not designate a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(b)(1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured in the advertisement for the drug; but, except as provided below in this subparagraph, the established name need not be used with the proprietary name or designation in the running text of the advertisement. On any page of an advertisement in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text in association with such proprietary name or designation and in the same type size used in the running text: Provided, however, That if the proprietary name or designation is used in the running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such running text. If any advertisement includes a column with running text containing detailed information as to composition, prescribing, side effects, or contraindications and the proprietary name or designation is used in such column but is not featured above or below the column, the established name shall be used at least once in such column of running text in association with such proprietary name or designation and in the same type size used in such column of running text: Provided, however, That if the proprietary name or designation is used in such column of running text in larger size type, the established name shall be used at least once in association with, and in type at

least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such column of running text. Where the established name is required to accompany or to be used in association with the proprietary name or designation, the established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as ``brand of'' preceding the established name, by brackets surrounding the established name, or by other suitable means.

(2) The established name shall be printed in letters that are at least half

[[Page 75]]

as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(c) In the case of a prescription drug containing two or more active ingredients, if the advertisement bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required in the advertisement by section 502(n) of the act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

(d)(1) If the advertisement employs one proprietary name or designation to refer to a combination of active ingredients present in more than one preparation (the individual preparations differing from each other as to quantities of active ingredients and/or the form of the finished preparation) and there is no established name corresponding to such proprietary name or designation, a listing showing the established names of the active ingredients shall be placed in direct conjunction with the most prominent display of such proprietary name or designation. The prominence of this listing of active ingredients shall bear a reasonable relationship to the prominence of the proprietary name and the relationship between such proprietary name or designation, and the listing of active ingredients shall be made clear by use of such phrase as ``brand of'', preceding the listing of active ingredients.

(2) The advertisement shall prominently display the name of at least one specific dosage form and shall have the quantitative ingredient information required by section 502(n) of the act in direct conjunction with such display. If other dosage forms are listed in the advertisement, the quantitative ingredient information for such dosage forms shall appear in direct conjunction and in equal prominence with the most prominent listing of the names of such dosage forms.

(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) When required. All advertisements for any prescription drug (``prescription drug'' as used in this section means drugs defined in section 503(b)(1) of the act and Sec. 201.105, applicable to drugs for use by man and veterinary drugs, respectively), except advertisements described in paragraph (e)(2) of this section, shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section ``side effects, contraindications'' include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness. Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of

the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications.

(2) Exempt advertisements. The following advertisements are exempt from the requirements of paragraph (e)(1) of this section under the conditions specified:

(i) Reminder advertisements. Reminder advertisements are those which call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product. These reminder advertisements shall contain only the proprietary name of the drug product, if any; the established name of the drug product, if any; the established name of each active ingredient in the drug product; and, optionally, information relating to quantitative ingredient statements, dosage form, quantity of

[[Page 76]]

package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug product. If the Commissioner finds that there is evidence of significant incidence of fatalities or serious injury associated with the use of a particular prescription drug, he may withdraw this exemption by so notifying the manufacturer, packer, or distributor of the drug by letter. Reminder advertisements, other than those solely intended to convey price information including, but not limited to, those subject to the requirements of Sec. 200.200 of this chapter, are not permitted for a prescription drug product whose labeling contains a boxed warning relating to a serious hazard associated with the use of the drug product. Reminder advertisements which are intended to provide consumers with information concerning the price charged for a prescription for a drug product are exempt from the requirements of this section if they meet all of the conditions contained in Sec. 200.200 of this chapter. Reminder advertisements, other than those subject to the requirements of Sec. 200.200 of this chapter, are not permitted for a drug for which an announcement has been published pursuant to a review on the labeling claims for the drug by the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group, and for which no claim has been evaluated as higher than ``possibly effective.'' If the Commissioner finds the circumstances are such that a reminder advertisement may be misleading to prescribers of drugs subject to NAS/NRC evaluation, such advertisements will not be allowed and the manufacturer, packer, or distributor will be notified either in the publication of the conclusions on the effectiveness of the drug or by letter.

(ii) Advertisements of bulk-sale drugs. Advertisements of bulk-sale drugs that promote sale of the drug in bulk packages in accordance with the practice of the trade solely to be processed, manufactured, labeled, or repackaged in substantial quantities and that contain no claims for the therapeutic safety or effectiveness of the drug.

(iii) Advertisements of prescription-compounding drugs. Advertisements of prescription-compounding drugs that promote sale of a drug for use as a prescription chemical or other compound for use by registered pharmacists in compounding prescriptions if the drug otherwise complies with the conditions for the labeling exemption contained in Sec. 201.120 and the advertisement contains no claims for the therapeutic safety or effectiveness of the drug.

(3) Scope of information to be included; applicability to the entire advertisement. (i) The requirement of a true statement of information relating to side effects, contraindications, and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in

another distinct part of the advertisement of a brief statement containing true information relating to side effects, contraindications, and effectiveness of the drug. If any part or theme of the advertisement would make the advertisement false or misleading by reason of the omission of appropriate qualification or pertinent information, that part or theme shall include the appropriate qualification or pertinent information, which may be concise if it is supplemented by a prominent reference on each page to the presence and location elsewhere in the advertisement of a more complete discussion of such qualification or information.

(ii) The information relating to effectiveness is not required to include information relating to all purposes for which the drug is intended but may optionally be limited to a true statement of the effectiveness of the drug for the selected purpose(s) for which the drug is recommended or suggested in the advertisement. The information relating to effectiveness shall include specific indications for use of the drug for purposes claimed in the advertisement; for example, when an advertisement contains a broad claim that a drug is an antibacterial agent, the advertisement shall name a type or types of infections and microorganisms for which the drug is effective clinically as specifically as

[[Page 77]]

required, approved, or permitted in the drug package labeling.

(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.; see paragraph (e)(1) of this section) contained in required, approved, or permitted labeling for the advertised drug dosage form(s): Provided, however,

(a) The side effects and contraindications disclosed may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement to the extent that such limited disclosure has previously been approved or permitted in drug labeling conforming to the provisions of Secs. 201.100 or 201.105; and

(b) The use of a single term for a group of side effects and contraindications (for example, ``blood dyscrasias'' for disclosure of ``leukopenia,'' ``agranulocytosis,'' and ``neutropenia'') is permitted only to the extent that the use of such a single term in place of disclosure of each specific side effect and contraindication has been previously approved or permitted in drug labeling conforming to the provisions of Secs. 201.100 or 201.105.

(4) Substance of information to be included in brief summary. (i)(a) An advertisement for a prescription drug covered by a new-drug application approved pursuant to section 505 of the act after October 10, 1962 or section 512 of the act after August 1, 1969, or any approved supplement thereto, shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement. The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

(b) If a prescription drug was covered by a new-drug application or a supplement thereto that became effective prior to October 10, 1962, an advertisement may recommend or suggest:

(1) Uses contained in the labeling accepted in such new-drug application and any effective, approved, or permitted supplement thereto.

(2) Additional uses contained in labeling in commercial use on October 9, 1962, to the extent that such uses did not cause the drug to

be an unapproved ``new drug'' as ``new drug'' was defined in section 201(p) of the act as then in force, and to the extent that such uses would be permitted were the drug subject to paragraph (e)(4)(iii) of this section.

(3) Additional uses contained in labeling in current commercial use to the extent that such uses do not cause the drug to be an unapproved ``new drug'' as defined in section 201(p) of the act as amended or a ``new animal drug'' as defined in section 201(v) of the act as amended.

The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

(ii) In the case of an advertisement for a prescription drug other than a drug the labeling of which causes it to be an unapproved ``new drug'' and other than drugs covered by paragraph (e)(4)(i) of this section, an advertisement may recommend and suggest the drug only for those uses contained in the labeling thereof:

(a) For which the drug is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of such drugs; or

(b) For which there exists substantial evidence of safety and effectiveness, consisting of adequate and well-controlled investigations, including clinical investigations (as used in this section ``clinical investigations,'' ``clinical experience,'' and ``clinical significance'' mean in the case of drugs intended for administration to man, investigations, experience, or significance in humans, and in the case of drugs intended for administration to

[[Page 78]]

other animals, investigations, experience, or significance in the specie or species for which the drug is advertised), by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses; or

(c) For which there exists substantial clinical experience (as used in this section this means substantial clinical experience adequately documented in medical literature or by other data (to be supplied to the Food and Drug Administration, if requested)), on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses; or

(d) For which safety is supported under any of the preceding clauses in paragraphs (e)(4)(iii) (a), (b), and (c) of this section and effectiveness is supported under any other of such clauses.

The advertisement shall present information relating to each specific side effect and contraindication that is required, approved, or permitted in the package labeling by Secs. 201.100 or 201.105 of this chapter of the drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

(5) ``True statement'' of information. An advertisement does not satisfy the requirement that it present a ``true statement'' of information in brief summary relating to side effects, contraindications, and effectiveness if:

(i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or

(ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by section 502(n) of the act and this information is not fairly

balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug; Provided, however, That no advertisement shall be considered to be in violation of this section if the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety.

(iii) It fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.

(6) Advertisements that are false, lacking in fair balance, or otherwise misleading. An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

(i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in this section patients means humans and in the case of veterinary drugs, other animals), safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraphs (e)(4)(ii) (b) and (c) of this section) whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

(iii) Contains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience.

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial

[[Page 79]]

evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

(vi) Contains references to literature or studies that misrepresent the effectiveness of a drug by failure to disclose that claimed results may be due to concomitant therapy, or by failure to disclose the credible information available concerning the extent to which claimed results may be due to placebo effect (information concerning placebo effect is not required unless the advertisement promotes the drug for use by man).

(vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

(viii) Uses a statement by a recognized authority that is apparently favorable about a drug but fails to refer to concurrent or more recent unfavorable data or statements from the same authority on the same subject or subjects.

(ix) Uses a quote or paraphrase out of context to convey a false or misleading idea.

(x) Uses literature, quotations, or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim.

(xi) Uses literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling.

(xii) Offers a combination of drugs for the treatment of patients suffering from a condition amenable to treatment by any of the components rather than limiting the indications for use to patients for whom concomitant therapy as provided by the fixed combination drug is indicated, unless such condition is included in the uses permitted under paragraph (e)(4) of this section.

(xiii) Uses a study on normal individuals without disclosing that the subjects were normal, unless the drug is intended for use on normal individuals.

(xiv) Uses ``statistics'' on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such ``statistics'' are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

(xv) Uses erroneously a statistical finding of ``no significant difference'' to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference.

(xvi) Uses statements or representations that a drug differs from or does not contain a named drug or category of drugs, or that it has a greater potency per unit of weight, in a way that suggests falsely or misleadingly or without substantial evidence or substantial clinical experience that the advertised drug is safer or more effective than such other drug or drugs.

(xvii) Uses data favorable to a drug derived from patients treated with dosages different from those recommended in approved or permitted labeling if the drug advertised is subject to section 505 of the act, or, in the case of other drugs, if the dosages employed were different from those recommended in the labeling and generally recognized as safe and effective. This provision is not intended to prevent citation of reports of studies that include some patients treated with dosages different from those authorized, if the results in such patients are not used.

(xviii) Uses headline, subheadline, or pictorial or other graphic matter in a way that is misleading.

(xix) Represents or suggests that drug dosages properly recommended for use in the treatment of certain classes of patients or disease conditions are safe and effective for the treatment of other classes of patients or disease conditions when such is not the case.

[[Page 80]]

(xx) Presents required information relating to side effects or contraindications by means of a general term for a group in place of disclosing each specific side effect and contraindication (for example employs the term blood dyscrasias instead of ``leukopenia,'' ``agranulocytosis,'' ``neutropenia,'' etc.) unless the use of such general term conforms to the provisions of paragraph (e)(3)(iii) of this section.

Provided, however, That any provision of this paragraph shall be waived with respect to a specified advertisement as set forth in a written communication from the Food and Drug Administration on a petition for such a waiver from a person who would be adversely affected by the enforcement of such provision on the basis of a showing that the advertisement is not false, lacking in fair balance, or otherwise

misleading, or otherwise violative of section 502(n) of the act. A petition for such a waiver shall set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of this paragraph from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act.

(7) Advertisements that may be false, lacking in fair balance, or otherwise misleading. An advertisement may be false, lacking in fair balance, or otherwise misleading or otherwise violative of section 502(n) of the act if it:

(i) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions.

(ii) Uses the concept of ``statistical significance'' to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results.

(iii) Uses statistical analyses and techniques on a retrospective basis to discover and **cite** findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

(iv) Uses tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied; for example, by failing to label abscissa and ordinate so that the graph creates a misleading impression.

(v) Uses reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles of statistical theory, methodology, applied practice, and inference, or that are derived from clinical studies the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretations, or evaluations.

(vi) Contains claims concerning the mechanism or site of drug action that are not generally regarded as established by scientific evidence by experts qualified by scientific training and experience without disclosing that the claims are not established and the limitations of the supporting evidence.

(vii) Fails to provide sufficient emphasis for the information relating to side effects and contraindications, when such information is contained in a distinct part of an advertisement, because of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.

(viii) Fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(ix) Fails to provide adequate emphasis (for example, by the use of color scheme, borders, headlines, or copy that extends across the gutter) for the fact that two facing pages are part of the same advertisement when one page contains information relating to side effects and contraindications.

(x) In an advertisement promoting use of the drug in a selected class of patients (for example, geriatric patients or depressed patients), fails to present with adequate emphasis the significant

[[Page 81]]

side effects and contraindications or the significant dosage considerations, when dosage recommendations are included in an advertisement, especially applicable to that selected class of patients.

(xi) Fails to present on a page facing another page (or on another full page) of an advertisement on more than one page, information relating to side effects and contraindications when such information is in a distinct part of the advertisement.

(xii) Fails to include on each page or spread of an advertisement the information relating to side effects and contraindications or a prominent reference to its presence and location when it is presented as a distinct part of an advertisement.

(xiii) Contains information from published or unpublished reports or opinions falsely or misleadingly represented or suggested to be authentic or authoritative.

(f)-(i) [Reserved]

(j)(1) No advertisement concerning a particular prescription drug may be disseminated without prior approval by the Food and Drug Administration if:

(i) The sponsor or the Food and Drug Administration has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage;

(ii) The Commissioner (or in his absence the officer acting as Commissioner), after evaluating the reliability of such information, has notified the sponsor that the information must be a part of the advertisements for the drug; and

(iii) The sponsor has failed within a reasonable time as specified in such notification to present to the Food and Drug Administration a program, adequate in light of the nature of the information, for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements.

If the Commissioner finds that the program presented is not being followed, he will notify the sponsor that prior approval of all advertisements for the particular drug will be required. Nothing in this paragraph is to be construed as limiting the Commissioner's or the Secretary's rights, as authorized by law, to issue publicity, to suspend any new-drug application, to decertify any antibiotic, or to recommend any regulatory action.

(2) Within a reasonable time after information concerning the possibility that a drug may cause fatalities or serious damage has been widely publicized in medical literature, the Food and Drug Administration shall notify the sponsor of the drug by mail that prior approval of advertisements for the drug is no longer necessary.

(3) Dissemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded under section 502(n) of the act.

(4) Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment. If the advertiser is notified that the submitted advertisement is not in violation and, at some subsequent time, the Food and Drug Administration changes its opinion, the advertiser will be so notified and will be given a reasonable time for correction before any regulatory action is taken under this section. Notification to the advertiser that a proposed advertisement is or is not considered to be in violation shall be in written form.

(5) The sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter with respect to any determination that prior approval is required for advertisements concerning a particular prescription drug, or that a particular advertisement is not approvable.

(k) An advertisement issued or caused to be issued by the manufacturer, packer, or distributor of the drug promoted by the advertisement and which is not in compliance with section 502(n) of the act and the applicable regulations thereunder shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded

under section 502(n) of the act.

[[Page 82]]

(1)(1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the ``Physicians Desk Reference'') for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

[40 FR 14016, Mar. 27, 1975, as amended at 40 FR 58799, Dec. 18, 1975; 41 FR 48266, Nov. 2, 1976; 42 FR 15674, Mar. 22, 1977; 60 FR 38480, July 27, 1995; 64 FR 400, Jan. 5, 1999]

Effective Date Note 1: At 44 FR 37467, June 26, 1979, Sec. 202.1(e)(6) (ii) and (vii) were revised. At 44 FR 74817, Dec. 18, 1979, paragraphs (e)(6) (ii) and (vii) were stayed indefinitely. For the convenience of the user, paragraphs (e)(6) (ii) and (vii), published at 44 FR 37467, are set forth below:

Sec. 202.1 Prescription-drug advertisements.

* * * * *

(e) * * *

(6) * * *

(ii) Represents or suggests that a prescription drug is safer or more effective than another drug in some particular when the difference has not been demonstrated by substantial evidence. An advertisement for a prescription drug may not, either directly or by implication, e.g., by use of comparative test data or reference to published reports, represent that the drug is safer or more effective than another drug, nor may an advertisement contain a quantitative statement of safety or effectiveness (a) unless the representation has been approved as part of the labeling in a new drug application or biologic license, or (b) if the drug is not a new drug or biologic, unless the representation of safety or effectiveness is supported by substantial evidence derived from adequate and well-controlled studies as defined in Sec. 314.111(a)(5)(ii) of this chapter, or unless the requirement for adequate and well-controlled studies is waived as provided in Sec. 314.111(a)(5)(ii) of this chapter.

* * * * *

(vii) Suggests, on the basis of favorable data or conclusions from nonclinical studies of a prescription drug, such as studies in laboratory animals or in vitro, that the studies have clinical significance, if clinical significance has not been demonstrated. Data that demonstrate activity or effectiveness for a prescription drug in animal or in vitro tests and have not been shown by adequate and well-controlled clinical studies to pertain to clinical use may be used in advertising except that (a), in the case of anti-infective drugs, in vitro data may be included in the advertisement, if data are immediately preceded by the statement ``The following in vitro data are available

but their clinical significance is unknown'' and (b), in the case of other drug classes, in vitro and animal data that have not been shown to pertain to clinical use by adequate and well-controlled clinical studies as defined in Sec. 314.111(a)(5)(ii) of this chapter may not be used unless the requirement for adequate and well-controlled studies is waived as provided in Sec. 314.111(a)(5)(ii) of this chapter.

* * * * *

Effective Date Note 2: At 64 FR 400, Jan. 5, 1999, Sec. 202.1 was amended by removing paragraph (e)(4)(ii) and redesignating paragraph (e)(4)(iii) as paragraph (e)(4)(ii), by removing the words ``paragraphs (e)(4)(i) and (ii)'' from newly redesignated paragraph (e)(4)(ii) and by adding in their place the words ``paragraph (e)(4)(i)'', by removing ``(e)(4)(iii)'' and by adding in its place ``(e)(4)(ii)'' in paragraph (e)(6)(i), by removing ``, 507, or 512'' from paragraph (e)(6)(xvii), by removing the phrase ``or antibiotic'' from indefinitely stayed paragraph (e)(6)(ii)(a); and by removing the phrase ``or a certified or released antibiotic,'' from indefinitely stayed paragraph (e)(6)(ii)(b), effective May 20, 1999. For the convenience of the user, the superseded text is set forth as follows:

Sec. 202.1 Prescription-drug advertisements.

* * * * *

(e) * * *
(4) * * *
(ii) An advertisement for a prescription drug subject to certification under section 507 or 512 of the act shall not recommend or suggest any use that is not in the labeling

[[Page 83]]

covered by the certification or the applicable certification regulations or regulations providing for exemption from certification. The advertisement shall present information from such labeling covered by the certification or the applicable certification regulations or regulations providing for exemption from certification, relating to each specific side effect and contraindication in such labeling and such regulations for the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

* * * * *

[Code of Federal Regulations]
[Title 21, Volume 5, Parts 300 to 499]
[Revised as of April 1, 1999]
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[**CITE: 21CFR314.550**]

[Page 178]

TITLE 21--FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES--Continued

PART 314--APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG--Table of Contents

Subpart H--Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses

Sec. 314.**550** Promotional materials.

For drug products being considered for approval under this subpart, unless otherwise informed by the agency, applicants must submit to the agency for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.