This is **Exhibit "A"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

**Biography – Richard O. Dolinar M.D.**

A private practice Clinical Endocrinologist in Phoenix, Arizona, Dr. Dolinar earned his Medical Degree from The State University of New York at Buffalo and did his Endocrinology Fellowship at Duke University. He received his undergraduate degree from Siena College in Albany, New York.

Dr. Dolinar has testified before the U.S. Senate Subcommittee on Consumer Affairs and has also given Congressional briefings on Capitol Hill regarding healthcare issues. He represented the American Association of Clinical Endocrinologists (AACE) at the public hearings regarding the Medicare Modernization Act of 2003 and the Medicare Drug Benefit. He has also presented to State Legislators as well as various healthcare industry professionals. Dr. Dolinar has been interviewed by both the local and national media, including CNN, CBS and PBS regarding his opinions on healthcare issues.

A published author, in both professional and consumer publications, his articles and opinion pieces have appeared in *The Wall Street Journal, USA Today, The New York Times, The New England Journal of Medicine, JAMA* (Journal of the American Medical Association) *Diabetes Research* and the *Indiana Health Law Review Journal.* His articles have also appeared on various web sites including The Heritage Foundation. He is co-author of the book, *Diabetes 101.*

Dr. Dolinar is a Member of the Board of Directors of AACE and serves on its National Legislative and Regulatory Committee. He is the Chair of its Future of Healthcare Committee. Dr. Dolinar serves as a Senior Fellow in Healthcare Policy at the Heartland Institute and has held leadership positions in other professional organizations including the Juvenile Diabetes Research Foundation and the American Diabetes Association. He is also on the Editorial Advisory Board for *Endocrine Today.*

Dr. Dolinar served as a Flight Surgeon in the Vietnam War and is a retired U.S. Air Force Colonel.

CURRICULUM VITAE

# RICHARD OWEN DOLINAR, M.D.

**14224 N. 11th Way**
**Phoenix, AZ 85022**
**Cell Phone: (602) 526-1235**
**E-mail: drdolinar@dolinar.org**

**Current Positions:**

Clinical Endocrinologist
In private practice since 1983
Arizona Endocrinology
5130 W. Thunderbird Road, Suite 1
Glendale, AZ 85306
Office (602) 439-9000

Senior Fellow in Healthcare Policy
Heartland Institute
Chicago, IL

National Board Member
American Association of Clinical Endocrinologists
Jacksonville, FL

Member of the Editorial Advisory Board
*Endocrine Today*

**Undergraduate Education:**

Siena College
Albany, New York
1964-1968
B.S. Biology Cum Laude

**Medical Education:**

State University of New York at Buffalo
1968-1972

**Internship:**

State University of New York at Buffalo
1972-1973
Medical Internship

**Residency:**

University of Rochester
Strong Memorial Hospital
Rochester, New York
1976-1977
Obstetrics and Gynecology Resident

| | | |
|---|---|---|
| **Residency:** | State University of New York at Buffalo<br>1978-1980<br>Medical Resident | |
| **Fellowship:** | Duke University Medical Center<br>Durham, North Carolina<br>1980-1983<br>Endocrinology Fellow | |
| **Special Training:** | U.S. Air Force School of Aerospace Medicine<br>Brooks Air Force Base, Texas<br>1973<br>Flight Surgeon | |
| | Walter J. Kempner Foundation<br>Duke University Medical Center<br>1981-1983<br>Obesity Research | |
| | U.S. Air Force Air War College<br>1992<br>Graduate | |
| **Awards and Scholarships:** | New York State Regents College Scholarship<br>Siena College Scholarship | |
| **College:** | Delta Epsilon Sigma National Scholastic Honor Society | |
| **Medical School:** | National Health Professions Scholarship | |
| **Board Certification:** | Diplomat of the American Board of Internal Medicine | |
| **Research Positions:** | 1983-2001 | Investigator<br>NIH-Diabetes Prevention Trial-I |
| | 1986-1993 | Director of Diabetes Research<br>Humana Hospital<br>Diabetes Center of Excellence |
| | 1997-2002 | Investigator for various pharmaceutical clinical studies |
| | 1998 | Research Consultant<br>MDS Harris<br>Phoenix, Arizona |

| | | |
|---|---|---|
| | 1999 | Research Consultant<br>Instrumentation Metrix<br>Tempe, Arizona |

**Licensed to Practice In:** Arizona

**Speakers Bureaus:** Eli Lilly & Company; Pharmaceutical Division
Pfizer Pharmaceuticals
Takeda Pharmaceutical Company

**Member of the Board:**

| | |
|---|---|
| 1983-1984 | Vice-President, Arizona Association of Diabetes Educators |
| 1984-1991 | American Diabetes Association - Arizona Affiliate<br>Board of Directors |
| 1985-1993 | Humana Hospital, Phoenix - Diabetes Center of Excellence<br>Advisory Board |
| 1986-Present | Juvenile Diabetes Research Foundation<br>State of Arizona Chapter |
| 1989-1991 | International Association of Diabetic Athletes<br>Board of Directors |
| 1996-1997 | Juvenile Diabetes Research Foundation<br>President, Arizona Chapter |
| 2005-Present | American Association of Clinical Endocrinologists<br>Board of Directors |

**Professional Society Memberships:**

| | |
|---|---|
| 1982-Present | American Medical Association |
| 1982-1984 | American College of Physicians |
| 1982-1991 | American Society of Internal Medicine |
| 1983-2001 | American Diabetes Association |
| 1983-Present | Arizona Medical Association |
| 1983-1994 | Arizona Association of Diabetes Educators |
| 1983-Present | Phoenix Cross Town Endocrine Society |
| 1984-1985 | American Association for the Advancement of Science |
| 1995-Present | American Association of Clinical Endocrinologists |
| 1996-Present | American Association of Physicians and Surgeons |
| 1997-1998 | National Health Lawyers Association |
| 1997-2000 | Society for the Education of Physicians and Patients |

**Civic Organizations:**

| | |
|---|---|
| 1982-Present | Air Force Association |
| 1983-Present | Reserve Officers Association |
| 1983-1992 | Scottsdale Arts Center Association |
| 1985-1988 | Executives International |
| 1998-Present | Red River Rats Fighter Pilots Association |

**Military Service:**

U.S. Air Force Flight Surgeon
1973-1974, Thailand/Vietnam
1974-1976, Spain
1979-1999, USAF Reserve

**Current Rank:**

Colonel, USAF Reserve Retired

**Military Awards:**

1988 Physician of the Year, IMA, USAF Reserve
USAF Commendation Medal
USAF Outstanding Unit Award
USAF National Defense Service Medal
USAF Overseas Long Tour Ribbon
USAF Longevity Service Ribbon
USAF Training Ribbon

**Governmental Affairs:**

| | |
|---|---|
| 1994-1997 | Managed Care Committee<br>Arizona Medical Clinic |
| 1995-1996 | Arizona Diabetes Control Counsel<br>Arizona Department of Health Services<br>Counsel Member |
| 1997 | Delegates for Diabetes<br>The American Diabetes Association<br>Advocacy Program |
| 1997 | Study Committee on Mandatory Insurance for Diabetes Treatment<br>State of Arizona<br>House of Representatives |
| 1997 | Physicians' Counsel<br>J.D. Hayworth<br>Congress of the United States<br>House of Representatives |

**Papers**

1. Srikanta, S., Telen, M., Reiman, T., Dolinar, R., Haynes, B., Eisenbarth, G.: Murine monoclonal antibody 4F-2: Binding to human pancreatic islet cells. Diabetologia 1982.

2. Dolinar, R., Burch, W.: Testosterone producing adrenal adenoma in a woman with
normal 17-ketosteroid levels.
JAMA: 1983; 250(18) 2504-2505.

3. Srikanta, S., Ganda, O.P., Rabizadeh, A., Soeldner, S., Eisenbarth, G.S.: First degree relatives of patients with type 1 diabetes: Islet cell antibodies and abnormal insulin secretion.
New England Journal of Medicine, 1985, 313(8): 461-464 (R. Dolinar, clinical collaborator.)

4. Eisenbarth, G.S., Srikanta, S., Jackson, R.A., Rabinowe, S.L., Dolinar, R., Aoki, T.T., Morris, M.A.: Anti-thymocyte globulin and prednisone immunotherapy of recent onset type 1 diabetes mellitus.
Diabetes Research 1985; 2,271-2,276.

5. Srikanta, S., Telen, M., Posillico, J.T., Dolinar, R., Krish, K. Haynes, B., Eisenbarth, G.: Monoclonal antibodies to a human cell surface glyco-protein; 4F-2 and LC-7-2.
Endocrinology 1987; 120, 2240-2244.

6. Vardi, P., Crisa, L., Jackson, R.A.: Predictive value of intravenous glucose tolerance test insulin secretion less than or greater than the first percentile in islet cell antibody positive relatives of type 1 (insulin-dependent) diabetic patients.
Diabetologia 1991, 34:93-102, (R. Dolinar, clinical collaborator.)

**Books**

1. Dolinar, R., Brackenridge, B., *Diabetes 101*, John Wiley & Sons, Inc. New York, New York, Minnetonka, Minn., 1989, 2nd edition 1993, Eastern European edition 1996, 3rd edition 1998.

**Law Review**

1. Dolinar, R., Leininger, S. Luke, *Pay For Performance or Compliance? A Second Opinion on Medicare Reimbursement*, Volume 3. Issue 2. P 397-420, 2006.

**Lay Media**

Dr. Dolinar has been interviewed by both the local and national media, including CNN, CBS and PBS regarding his opinions on healthcare issues.

His articles and opinion pieces have appeared in *The Wall Street Journal, USA Today, The New York Times* and in various local newspapers. His articles have also appeared on various web sites including The Heritage Foundation.

This is **Exhibit "B"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

# 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*

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

*or*
*Communications Staff (HFV-12)*
*Center for Veterinary Medicine (CVM)*
*7500 Standish Place, Rockville, MD 20855 (Tel) 301-594-1755*
*http://www.fda.gov/cvm*

**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[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.

This is **Exhibit "C"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

ANNUAL BURDEN ESTIMATES

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

*Estimated Total Annual Burden Hours:* 440.

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

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

Dated: September 7, 2005.

**Robert Sargis,**

*Reports Clearance Officer.*

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

BILLING CODE 4184–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005N–0354]**

### Consumer-Directed Promotion of Regulated Medical Products; Public Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; request for comments.

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

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

*Location:* The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594, 202–314–6421; Metro: L'Enfant Plaza station on the green, yellow, blue, and orange lines; see: *http://ntsb.gov/events/newlocation.htm.* (FDA has verified the Web site address, but FDA is not responsible for any changes to the Web site after this document publishes in the **Federal Register**.)

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

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

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

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

A written statement also should be submitted at the time of registration for each discussion question to be addressed, with the names and addresses of all individuals who plan to participate, and the approximate time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. Individuals who have registered to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. Depending on the number of presentations, FDA may need to limit the time allotted for each presentation. FDA has identified questions and subject matter of special interest in section III of this document, but presentations do not have to be limited to those questions. Presenters should

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

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

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. Definition of Terms and Regulatory Requirements*

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

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

FDA regulates the labeling of all drugs and devices under its jurisdiction. Labeling must be truthful and nonmisleading (section 502(a) of the act (21 U.S.C. 352(a)). For human and veterinary prescription drugs, labeling must contain adequate directions/information for use that is the "same in language and emphasis" as the product's approved or permitted labeling (21 U.S.C. 352(f)) and 21 CFR 201.100(d) and 201.105(d)). This requirement is generally fulfilled by including the full approved labeling for the product (the "package insert") with the promotional materials. For devices, the requirement of 21 U.S.C. 352(f) applies as well, and a device is misbranded unless its labeling bears adequate instructions for use. A device that is safe only if used under the supervision of a licensed practitioner and for which adequate instructions for use can therefore not be provided, is exempt from this requirement if, among other things, all of its labeling that purports to furnish information on the use of the device also contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which licensed practitioners can safely use the device for the purposes for which it is intended.

Although the act does not define what constitutes a prescription drug "advertisement," FDA generally interprets the term to include information (other than labeling) that is issued by, or on behalf of, a manufacturer, packer, or distributor and is intended to promote a product. This includes, for example, "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (§ 202.1(l)(1)).

The act specifies that, in addition to the identity of the product and its quantitative composition, prescription drug advertisements must contain "other information in brief summary relating to side effects, contraindications, and effectiveness * * * " (21 U.S.C. 352(n)). FDA further defines this latter requirement in § 202.1(e). This requirement frequently is fulfilled by including the sections of the approved labeling that discuss the product's adverse event profile, contraindications, warnings, and precautions. In addition, the act and regulations specify that drugs are considered to be misbranded if their labeling or advertising is false or misleading in any particular or fails to reveal material facts (21 U.S.C. 352(a) and section 201(a) of the act (21 U.S.C. 321(n)), and § 202.1(e)).

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

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

### *B. History of DTC Promotion*

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

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

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

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

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

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

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

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

### *C. Implementation of Current Regulations*

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

### *D. Pending Citizen Petitions*

We note that FDA has received a number of citizen petitions that address DTC promotion. The positions advocated by these petitions vary considerably. One petition (Docket No. 1991P–0337) requests that FDA ban direct-to-consumer advertising of prescription drugs. A second petition (Docket No. 1991P–0227) requests that FDA not adopt or institute any significant new restrictions to existing regulations nor mandate prior approval of consumer-directed advertising. A third petition (Docket Nos. 1989P–0505 and 1995P–0104), updated and reissued by the petitioner, maintains that consumer-directed prescription drug advertising should not be regulated under § 202.1. It also maintains: (1) That FDA should issue new regulations to address prescription drug advertisements directed to consumers and (2) that until such time as new regulations are established, FDA should issue a policy statement and regulation stating that prescription drug advertisements directed to the general public are exempt from the advertising regulations under § 202.1. Finally, two petitions (Docket No. 1995P–0224/CP1 & CP2) reference and reiterate requests of earlier petitions to stop regulating DTC advertising under § 202.1 and also maintain that such regulations violate the First Amendment. Consistent with 21 CFR 10.30(h)(2), FDA intends to use this public hearing to further explore the issues raised in these citizen petitions and hereby incorporates the records in these citizen petition dockets into this docket.

## II. Purpose and Scope of the Hearing

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

## III. Issues for Discussion

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

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

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

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

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

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

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

• *Presentation of risk information*

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

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

• *Use of certain standard advertising strategies*

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

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

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

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

- *Use of comparative DTC promotion*

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

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

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

Advertisements that make claims about the product must include a "true statement of * * * other information in brief summary relating to side effects, contraindications, and effectiveness" (21 U.S.C. 352(n)). This statement is known as the "brief summary." This requirement is generally satisfied by reprinting the relevant sections of the package insert as the brief summary and, for this reason, its value for consumers is also questionable. As discussed in section II of this document, FDA has issued a draft guidance entitled "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements." The draft guidance gives several recommended alternatives to reprinting parts of the package insert as the brief summary for DTC prescription drug print advertisements. FDA is considering the comments that have been submitted to the Docket, but is interested in any additional comments on these brief summary recommendations and on other brief summary alternatives that would make the required disclosure more understandable to consumers.

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

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

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

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

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

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

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

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

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

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

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

6. What action should FDA take when companies disseminate violative promotional material to consumers?

For most prescription drugs and all devices, there is no requirement that companies submit their promotional materials to FDA before using them, and the U.S. Constitution limits the agency's ability to preclear promotional materials. Rather, companies must submit prescription drug promotional pieces at the time of their initial use in public. Device promotional pieces are not subject to a submission requirement. Under section 502(n) of the act, FDA can require that sponsors obtain preapproval of prescription drug advertisements only in "extraordinary circumstances." As a result, FDA's review of promotional materials is almost wholly post hoc, (i.e., after the materials have already appeared in public). Consequently, any enforcement action that FDA takes will also be post hoc.

Most of FDA's enforcement actions ask sponsors to stop using the violative materials. In some cases, for both professional- and consumer-directed pieces, FDA also asks sponsors to run corrective advertisements or issue corrective promotional materials to remedy misimpressions created by false or misleading materials. The agency is interested in hearing views on this type of enforcement approach for consumer-directed promotional materials as well as other enforcement approaches that might protect the public health.

## IV. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15. The Commissioner will designate a presiding officer, who will be accompanied by senior management from the Office of the Commissioner, the Center for Biologics Evaluation and Research, CDER, CDRH, and the Center for Veterinary Medicine.

Persons who wish to make an oral presentation during the part 15 hearing must file a written or electronic notice of participation with the Division of Dockets Management (see *Addresses*). To ensure timely handling, any outer envelope or subject heading should be clearly marked with the docket number found in brackets in the heading of this document along with the statement "Consumer-Directed Promotion of Medical Products." Groups should submit two written copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation (including the specific discussion questions that will be addressed); and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. FDA asks that participants set aside both days of the meeting so that the agency can group presentations on similar topics. The agency will let the participants know as soon as possible the time and date the participant is scheduled to present. FDA may also ask participants to rank order presentation topics, and FDA may need to restrict the time allotted to each participant. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Division of Dockets Management under the docket number found in brackets in the heading of this document.

Because of limited seating at the conference facility, FDA requests that organizations restrict their number of attendees at the meeting to five.

Under § 15.30, the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see *For further information contact*).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

## V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic notices of participation and comments for consideration at the hearing. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions to which they refer (see section III of this document). Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number at the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the hearing also will be available for review at the Division of Dockets Management.

## VI. Transcripts

The transcript of the hearing will be available 30 days after the hearing on the Internet at *http://www.fda.gov/ohrms/dockets*, and orders for copies of the transcript can be placed at the meeting or through the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Dated: September 6, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–18040 Filed 9–9–05; 8:52 am]

BILLING CODE 4160–01–S

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

**[DHS–2005–0061]**

### Data Privacy and Integrity Advisory Committee

**AGENCY:** Office of the Secretary, Department of Homeland Security.

This is **Exhibit "D"** referred to in the Affidavit of **Dr. Richard Dolinar** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

CINDY TROWBRIDGE
Notary Public - Arizona
MARICOPA COUNTY
My Commission Expires
OCTOBER 5, 2007

# Federal Food, Drug, and Cosmetic Act

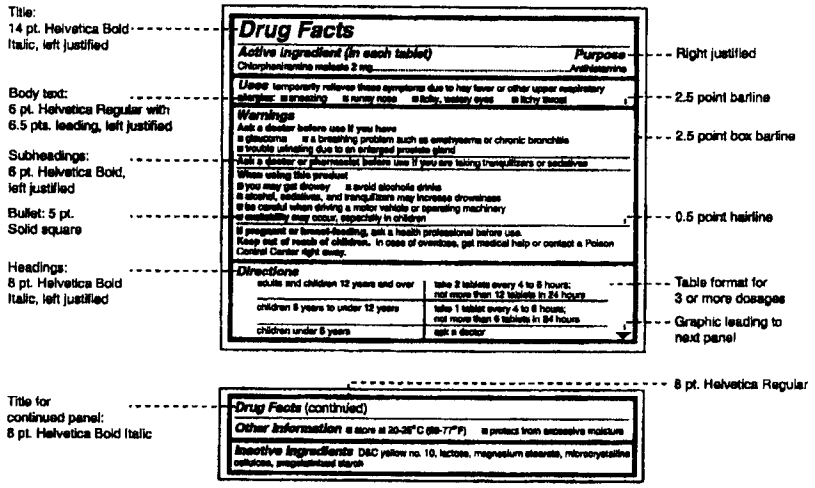
## CHAPTER V—DRUGS AND DEVICES
## SUBCHAPTER A—DRUGS AND DEVICES

### MISBRANDED DRUGS AND DEVICES

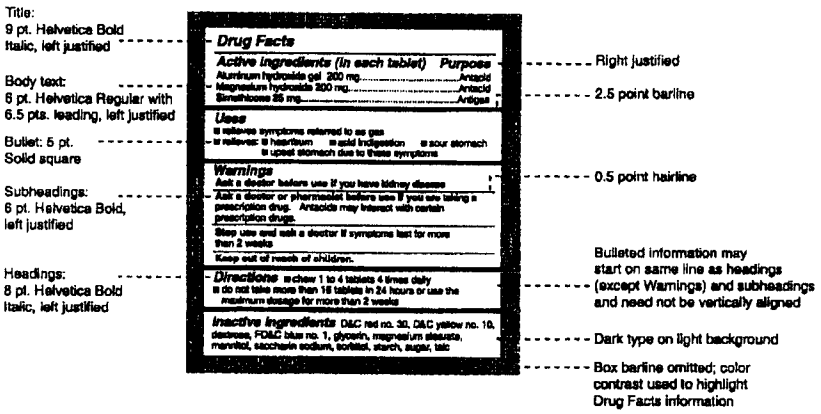
**SEC. 502.** [21 U.S.C. 352] A drug or device shall be deemed to be misbranded—

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e) 6, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) 6, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph (n) 7 shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. 8

**A. Section 201.66 Standard Labeling Format**




**B. Section 201.66 Modified Labeling Format**




## PART 202—PRESCRIPTION DRUG ADVERTISING

AUTHORITY: 21 U.S.C. 321, 331, 352, 355, 360b, 371.

### § 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 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 §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 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 §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 §200.200 of this chapter. Reminder advertisements, other than those subject to the requirements of §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 §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 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 §§ 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 §§ 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 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 §§ 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 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.

(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 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.

(l)(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: At 44 FR 37467, June 26, 1979, §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. At 64 FR 400, Jan. 5, 1999, these paragraphs were amended. For the convenience of the user, paragraphs (e)(6) (ii) and (vii), published at 44 FR 37467, are set forth below:

**§ 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 §314.111(a)(5)(ii) of this chapter, or unless the requirement for adequate and well-controlled studies is waived as provided in §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 §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 §314.111(a)(5)(ii) of this chapter.

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# PART 203—PRESCRIPTION DRUG MARKETING

## Subpart A—General Provisions

Sec.


## Subpart B—Reimportation



## Subpart C—Sales Restrictions



## Subpart D—Samples