

ADVERTISING, MARKETING & PROMOTIONS

>> ALERT

PHARMA AMENDS VOLUNTARY GUIDELINES ON DTC ADVERTISING

Last December, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced that it had revised, and thereby strengthened, its voluntary guidelines for members relating to direct to consumer (DTC) advertising, *PhRMA Guiding Principles, Direct to Consumer Advertisements About Prescription Medicines* (the Guiding Principles).

PhRMA, an organization that represents many of the country's pharmaceutical research and biotechnology companies, established the Guiding Principles in 2005 to "express the commitment of its members to deliver direct to consumer communications that serve as valuable contributors to public health." PhRMA has long maintained that DTC advertising is beneficial both to patients and doctors and has stated that the revisions reflect feedback received from interested parties. It is worth noting that the revisions come at a time when DTC advertising is receiving much criticism from interested parties, including members of Congress.

The revisions to the Guiding Principles become effective on March 2, 2009 and address various issues including:

>> Consideration of Feedback

Companies are advised to gauge the educational impact of

advertising campaigns by seeking and considering feedback from appropriate audiences, such as health care professionals and patients, during development.

>> Education of Healthcare Professionals

Companies are encouraged to set specific periods of time before the launch of branded advertising campaigns to educate healthcare professionals.

>> FDA's Toll-Free MedWatch Telephone Number

A new guiding principle was added that addresses the inclusion of FDA's toll-free MedWatch telephone number and website for reporting potential adverse events in print advertisements, and the inclusion of a reference to such a print advertisement in television commercials.

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THE BOTTOM LINE

DTC advertising has remained under siege since it began proliferating in the United States after regulations affecting it were eased in 1997. The revised Guiding Principles are but one step in assuaging the outspoken opponents of DTC advertising. Expect pharmaceutical companies to start tightening up their advertising practices, not only in light of the revised Guiding Principles, but also in an attempt to avoid future legislative or regulatory restriction.

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>> Advertisements Featuring Healthcare Professionals

A new guiding principle was added that states that advertisements featuring actors playing the role of healthcare professionals should acknowledge actors are being used, and that advertisements featuring actual healthcare professionals should acknowledge if the healthcare professionals are compensated.

>> Celebrity Endorsements

A new guiding principle was added that states that celebrity endorsements should accurately reflect the opinions, findings, beliefs or experience of the celebrity endorser.

>> Appropriate Audiences

Companies are advised that advertisements containing material inappropriate for children should be placed in programs or publications reasonably expected to draw an audience of approximately 90% adults.

The Questions and Answers section of the Guiding Principles, which provides further guidance relating to individual principles, has also been revised to address the above-mentioned changes.

The complete revised Guiding Principles may be found at www.phrma.org/files/PhRMA%20Guiding%20Principles_Dec%2008_FINAL.pdf and so far the

following companies have pledged to abide by them:

Abbott
Amgen, Inc.
Amylin Pharmaceuticals, Inc.
Astellas US LLC
AstraZeneca LP
Bayer HealthCare Pharmaceuticals
Boehringer Ingelheim Pharmaceuticals, Inc.
Bristol-Myers Squibb Company
Daiichi Sankyo, Inc.
Eisai Inc.
Eli Lilly and Company
EMD Serono
Genzyme Corporation
GlaxoSmithKline
Hoffman-La Roche, Inc.
Johnson & Johnson
Merck & Co., Inc.
Novartis Pharmaceuticals Corporation
Pfizer Inc.
Sanofi-aventis U.S.
Schering-Plough Corporation
Solvay Pharmaceuticals, Inc.
Takeda Pharmaceuticals North America, Inc.
Wyeth

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