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FDA GUIDANCE FOR "DTC" ADS STRIVES TO ADVANCE CONSUMER UNDERSTANDING

by
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The Food and Drug Administration ("FDA") has taken significant symbolic steps in recognizing the need for, and value of, effective communication to consumers about prescription drugs and certain medical devices. The agency has adopted three new "draft guidances" that propose to give drug and device companies more flexibility to send clear and simple promotional messages to laypersons. In a clear break from FDA's historical focus on detailed and precise disclosures aimed at doctors, Commissioner Mark McClellan said the proposed simplification of the "brief summary" of risk information in print advertising reflected the agency's understanding that "less is more" in terms of consumer comprehension.

In addition to the draft guidance concerning risk information requirements for "direct to consumer" ("DTC") advertisements, 69 Fed. Reg. ___ (publication pending), FDA released proposed guidances addressing (1) non-branded "help-seeking" ads and other health-awareness messages, 69 Fed. Reg. ___, and (2) broadcast advertisements for "restricted" devices, which require use by, or supervision of, a licensed medical professional, 69 Fed. Reg. 6308 (Feb. 10, 2004).

Announcing the release of the drafts on Feb. 4, 2004, Commissioner McClellan said that the agency understands that DTC disclosures need to be simpler and clearer to better advance the public understanding of treatable conditions such as diabetes, high blood pressure, high cholesterol and depression. FDA also now recognizes that the communicative effectiveness of DTC advertising is important because "evidence shows that promotions directed to consumers can play a particularly important role in helping patients start a discussion with their health practitioner about many conditions that are often unrecognized and are under-treated in this country."

At a Feb. 10, 2004 meeting sponsored by Parade Magazine in New York City, Peter Pitts, FDA's Associate Commissioner for External Relations, and other senior staff took the message to Madison Avenue. "As we enter our second century," Pitts said, "our mission has evolved to 'protecting and advancing America's health.'" He expressed his hope that this is "just the beginning of a dynamic new dialogue" between the FDA and drug marketers to advance the public health potential of DTC advertising.

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The draft guidance dealing with DTC print ads presents drug manufacturers with several alternatives for presenting risk information to consumers. At the New York meeting, both Pitts and Robert Temple, director of the FDA Office of Medical Policy, jokingly acknowledged that the currently required "brief summary" of risk disclosures is neither brief nor a summary. Most drug manufacturers have satisfied this requirement by reproducing the lengthy, highly technical FDA-approved professional labeling.

Under the relaxed risk information directive, manufacturers could replace the brief summary with consumer-friendly language that includes all contraindications, all warnings, "major precautions," and the three to five most common non-serious side effects of the advertised drug. FDA hopes the public comments will include further data about consumer responses to risk information and has made it clear it is open to alternative approaches to presenting health information effectively to consumers.

The draft guidance on help-seeking ads clarifies the criteria FDA uses to distinguish between these and drug ads. The former provide information that enables consumers to recognize the symptoms of a treatable disease but do not mention the name of a drug. Because help-seeking ads do not promote any particular product for the treatment of that disease, they are not subject to FDA's risk disclosure requirements. Although the FDA staff at the New York meeting strongly encouraged drug marketers to use more help seeking ads, the draft guidance focuses on enforcement. The guidance strongly warns manufacturers to avoid situations that appear to skirt the rules. It notes, for example, that some help-seeking ads appear closely linked in time, space or style with explicit product-promotion messages and thereby function as regulated advertising.

FDA's draft guidance on broadcast ads for restricted devices largely reinforces unofficial guidance on risk disclosure information that the agency staff has been providing to the industry for the past few years. Much like FDA's 1999 guidance for commercials concerning prescription drugs, the draft guidance for restricted devices requires that broadcast ads for the products present a "major statement" of product risks and provide "adequate provision" to obtain complete risk information, such as a toll-free telephone number or web site.

As a practical matter, manufacturers can expect FDA to evaluate ads with an eye to these guidances immediately, despite the fact that they are subject to further comment and change. Although guidances are not legally binding on either FDA or the public, they offer a "safe harbor" for compliance purposes, and have much of the effect of an agency rule.

FDA's modified approach to the brief summary of risk information in print ads marks the most dramatic change in regulation, and it is the one the FDA hopes will most advance consumer understanding. Left to be seen, however, is how often drug manufacturers will actually use the new regulatory flexibility for print ads. The draft guidance does not address a related concern of manufacturers: the growing threat of product liability suits brought against manufacturers on the basis of representations — or omissions — in their DTC ads.

Pitts alluded to this issue during the New York meeting by saying that much current risk information is "neither designed nor delivered to be user-friendly" but challenging the audience to create ads that are "both user-friendly and in full compliance" with FDA rules. The current rash of consumer class action and other non-FDA challenges to drug company marketing, however, may require the development of additional protection at the federal level against state law actions based on FDA-compliant advertising.

Comments on the draft guidance about medical device ads are due by May 10, 2004, and deadlines for input on the other two proposals likely will fall shortly thereafter. All three documents are available on FDA's website. *See* http://www.fda.gov/cder/guidance/5669dft.pdf (risk information in print advertisements); http://www.fda.gov/cder/guidance/6019dft.pdf (help-seeking ads); and http://www.fda.gov/cdrh/comp/guidance/1513.pdf (broadcast ads for restricted devices).

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