DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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November 1, 2001

Daniel J. Popeo
Paul D. Kamenar
Washington Legal Foundation
2009 Massachusetts Avenue, N.W.
Washington, DC 20036

Re: Docket No. 01P-0187/CP 1

Dear Messers. Popeo and Kamenar:

This letter responds to your citizen petition, received by the Food and Drug Administration (FDA) on April 16, 2001, filed on behalf of the Washington Legal Foundation. Your petition asked FDA to "formally adopt a rule, policy, or guidance stating that information presented or available on a company's Internet website, including hyperlinks to other third party sites, does not constitute 'labeling,'" as defined by the Federal Food, Drug, and Cosmetic Act (FDCA) at 21 U.S.C. § 321(m). In your petition, you further requested that the rule, policy, or guidance specify that such information may, but does not necessarily, constitute advertising. Alternatively, you asked FDA to adopt a rule, policy, or guidance "exempting Internet information of food companies from labeling requirements."

FDA agrees that Internet information, particularly those websites that provide truthful and non-misleading information about FDA-regulated products, can serve a valuable and useful function. The agency also agrees that it has not issued a specific rule, policy, or guidance that addresses whether information posted on a company's website is considered advertising, labeling, neither, or both. However, FDA disagrees that information presented or available on a company's website could never constitute labeling.

"Labeling" is defined in section 201(m) of the FDCA (21 U.S.C. § 321(m)) as "all labels and other written, printed or graphic matter upon any article... or accompanying such article." In *Kordel v. United States*, 335 U.S. 345 (1948), the Supreme Court concluded that the phrase "accompanying such article" included literature that was shipped separately and at different times from the drugs with which they were associated. "One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant." Id. at 350. The Court also noted that the literature and drugs were parts of an integrated distribution program.

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Based on this authority, FDA and the courts have interpreted "labeling" to include "[b]rochures, booklets, ... motion picture films, film strips, ... sound recordings, ... and similar pieces of printed, audio, or visual matter descriptive of a drug... which are disseminated by or on behalf of its manufacturer, packer, or distributor...." 21 C.F.R. § 202.1(l)(2); *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F. 3d 21, 26 (2d Cir. 2000) (dictum) (copyrighted user's guide and audiotape for nicotine gum constitute "labeling").

Lower court cases after *Kordel* reinforce a broad reading of the term "accompanying." *See United States v. Diapulse Manufacturing Corp. of America*, 389 F. 2d 612 (2d Cir. 1968); *V.E. Irons, Inc. v. United States*, 244 F. 2d 34 (1st Cir. 1957), cert. denied, 77 S. Ct. 1383 (1957). In addition, the courts have considered whether the information and the product are part of an integrated distribution program, where, for example, the information and the product originate from the same source or the information is designed to promote the distribution and sale of the product, even if such sale is not immediate. *See United States v. 47 Bottles, More or Less, Jenasol RJ Formula "60"*, 320 F. 2d 564 (3d Cir. 1963); *United States v. Guardian Chemical*, 410 F.2d 157 (2d Cir. 1969).

Accordingly, FDA believes that, in certain circumstances, information about FDA-regulated products that is disseminated over the Internet by, or on behalf of, a regulated company can meet the definition of labeling in section 201(m) of the FDCA. For example, if a company were to promote a regulated product on its website and allow consumers to purchase the product directly from the website, the website is likely to be "labeling." The website, in that case, would be written, printed, or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product.

To provide an example from the other end of the spectrum, some product-specific promotion presented on non-company websites that is very much similar, if not identical, to messages the agency has traditionally regulated as advertisements in print media (e.g., advertisements published in journals, magazines, periodicals, and newspapers) would be viewed as advertising. These are just examples at the extremes and, as discussed below, the agency will proceed on case-by-case basis in determining what is "labeling."

The agency sees no reason to treat Internet information of food companies differently from Internet information of other FDA-regulated industries. As such, FDA disagrees with your alternative request to exempt Internet information of food companies from labeling requirements.

Government agencies possess broad discretion in deciding whether to proceed by general rulemaking or case-by-case adjudication. *NLRB v. Bell Aerospace Co., Div. of Textron, Inc.* 416 U.S. 267, 294 (1974); *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947); *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F. 3d 1003, 1010 (D.C. Cir. 1999). FDA has explored developing a guidance on promotion of FDA-regulated products on the Internet, but has decided not to issue a document at this time. The agency believes that any rule or

guidance on this issue would be quickly outdated due to the ongoing rapid changes in the Internet and its use. As a result, issuing a rule or guidance may stifle innovation and create greater confusion among industry and the public. Therefore, for the time being, FDA will continue to use a case-by-case approach based on the specific facts of each case.

Although for the reasons stated above, FDA has decided to deny your petition, generally, at a company's request, the agency is willing to discuss a company's specific plans for posting information on its website or linking to information on a third-party website.

FDA appreciates your interest in this area.

Sincerely yours,

Margaret M. Dotzel
Associate Commissioner
for Policy