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July 23, 1998

BY HAND

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

1830 98 JUL 23 4:00

Re: Dissemination of Information on Unapproved/New
Uses for Marketed Drugs, Biologics and Devices
Docket 98N-0222

Dear Sir/Madam:

We represent C. B. Fleet Company, Incorporated, of Lynchburg, Virginia (Fleet).

We are submitting on behalf of Fleet the following comments in response to the Notice of Proposed Rulemaking on the dissemination of information about unapproved or new uses for marketed drugs, biologics and devices, published by the Food and Drug Administration (FDA) on June 8, 1998. 63 Fed. Reg. 31143.

The proposed rule is intended to implement the dissemination provisions of the FDA Modernization Act (FDAMA), which was signed into law on November 21, 1997, permitting dissemination of such information. The proposed regulations describe the information about unapproved uses that a manufacturer may disseminate, the procedures

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for the submissions to the Agency that must be made before information on such a use may be disseminated, the actions that FDA will take in response to such submissions, and recordkeeping and reporting requirements. Under the proposed rule, a manufacturer may disseminate written information about the safety, effectiveness or benefit of a new, but unapproved, use of an approved drug or device under certain limited circumstances.

The proposed rule does not contain a definition of the term “approved.” FDA has apparently taken the position that Over-the-Counter drugs that are marketed subject to Final Monographs are not “approved” products, and that the proposed rule would therefore not permit manufacturers of OTC drugs to disseminate written information about the safety, effectiveness or benefits of a non-monograph professional use of such a drug, even where the information meets the stringent restrictions contained in the proposed dissemination rule, and where the manufacturer made a commitment as required by the proposed rules to submit an NDA for the use.

We do not believe that such a narrow interpretation of the term “approved” serves the purposes of the provision of FDAMA that the proposed regulations are intended to implement. It was clearly Congress’ intention that manufacturers and distributors of

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legally marketed drugs and devices be able to disseminate to health care providers and related entities certain reliable information about off-label uses of those products.^{1/}

FDA has permitted OTC drugs to be marketed to professionals. For example, professional labeling is incorporated in the OTC Final Monographs for antacids, 21 C.F.R. §331.80, antiflatulents, 21 C.F.R. §332.31, antimicrobial, 21 C.F.R. §333.280, antiemetics, 21 C.F.R. §336.80, cough/cold/allergy products, 21 C.F.R. § 341.90, ophthalmic products, 21 C.F.R. §349.80, anticaries products, 21 C.F.R. §355.60, anthelmintics, 21 C.F.R. §357.180, and cholecystokinetics, 21 C.F.R. §357.280.

Professional labeling has been proposed for many other categories of OTC drug products, including laxative drug products. As off-label professional uses of OTC drugs may be just as important, from a medical perspective, as off-label uses of prescription drugs, it makes sense to, and complies with the intent of FDAMA, include legally marketed OTC drugs as “approved” drug products for which such unapproved uses can be legally disseminated to health care providers and related entities.

^{1/} See, e.g., 63 Fed. Reg. at 31151, discussing Congress’ concern with the need to get potentially important information on new uses to physicians. Fleet does not, however, contend that such unapproved uses should be able to be made to consumers, as that would be inconsistent with Congressional intent.

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Further, OTC drugs subject to Final Monographs are, in a very real sense, “approved.” FDA expert panels have reviewed the information available on the products’ active ingredients and have determined that the information was sufficient to support a finding that the products are generally recognized as safe and effective for specific indications. FDA has reviewed the reports of these panels and issued rules accepting their recommendations, and approving the use of products for certain indications. For that reason, FDA permits an OTC drug manufacturer who complies with the wording of a Final Monograph to use a label stating that the information on the label is “FDA approved.” See 21 C.F.R. § 330.1(c)(2)(1).

It is our understanding that FDA may include devices that have been cleared pursuant to § 510(k) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360(k), within the definition of an “approved” product. See M-D-D-I Reports, *The Gray Sheet*, July 13, 1998, p. 10, a copy of which is attached. We respectfully submit that an OTC drug subject to a Final Monograph, or marketed in compliance with a Tentative Final Monograph, is more properly characterized as “approved” than is a device subject to a premarket notification, which in many cases simply acknowledges that the device is substantially equivalent to a device that was legally marketed prior to the enactment of the Medical Device Amendments in 1976.

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For the above reasons, Fleet believes that the proposed rule should permit the dissemination of unapproved *professional* uses of OTC drugs otherwise marketed in compliance with Final Monographs or Tentative Final Monographs subject to the other requirements of the proposed rule. As with 510(k) notifications, FDA's apparent interpretation of FDAMA is overly technical and is not consistent with Congressional intent. Fleet, therefore, requests that the Final Rule, when published, be amended accordingly.

We thank you for your consideration of these comments.

Sincerely,



Peter S. Reichertz

Counsel to C. B. Fleet Company, Incorporated

(in triplicate)

Enclosure

**THIS DOCUMENT IS NOT INCLUDED BECAUSE IT
CONTAINS COPYRIGHT MATERIALS**

**DOCKET
98N-0222**

**ON
FDAMA SECTION 401 DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES**

Comment 21

**OFF-LABEL DISSEMINATION RULE'S "SUPPLEMENT" DEFINITION MAY BE REVISITED; The Gray
Sheet, v24;No. 28, p10, 7/13/98**

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