

July 21, 2004

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Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

E. Edward Kavanaugh  
President

Re: Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Docket No. 2003N-0342

Dear Sir or Madam:

These comments are submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA)<sup>1</sup> in response to FDA's proposed rule "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products," published in 69 Fed. Reg. 21778 (April 22, 2004) (Rule).

In the *Federal Register* of April 22, 2004, the Food and Drug Administration (FDA) proposed a new rule that would require human drug products for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act to be labeled with a toll-free number that is to be used only for reporting side effects and not for medical advice. The proposed rule is intended to implement the labeling requirements of Public Law 107-109, the Best Pharmaceuticals for Children Act (BPCA). As written, it would include reporting adverse experiences for over-the-counter (OTC) drug products marketed under an approved drug application in addition to prescription drug products.

Many CTFA members manufacture and distribute products that are regulated both as cosmetics *and* as over-the-counter drug products. These products, such as acne remedies, skin protectants, antimicrobial soaps and sunscreens, provide valuable health benefits to consumers in a variety of personal care products designed for daily use. Of the drug products that CTFA members manufacture and market, the vast majority of them are marketed subject to the monograph drug regulations; however, some of our members also manufacture and market drugs under approved drug applications. For these reasons we are filing comments in response to the Rule.

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<sup>1</sup> CTFA is the national trade association representing the personal care product industry. Founded in 1894, CTFA represents almost 600 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States, as well as a large number of OTC drug products and products that are both drugs and cosmetics. CTFA also includes associate member companies from related industries, including manufacturers of raw materials, packaging materials, and research testing laboratories.

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A. FDA should exclude nonprescription drugs from the 800 toll-free number requirement

There is evidence to suggest that in the drafting of section 17 of the Amendment, Congress intended to apply the 800 toll-free number labeling requirement to prescription drugs only. This interpretation is supported by the legislative history of the BPCA which references the impact on pharmacists of requiring this labeling for prescription drugs and acknowledges the need for flexibility to permit pharmacists to comply with the Rule, without corresponding references to the impact on OTC drugs. For these reasons, as written, the proposed Rule inappropriately amends the labeling regulations for OTC drugs approved under an application.

B. The Rule will confuse consumers

Section 17 of the BPCA requires FDA to issue a final rule mandating that the labeling of each drug approved under section 505 include a toll-free number for reporting adverse events regarding drugs and a statement that the number is for reporting purposes only, *i.e.*, not to seek medical advice. The 1-800 number is the FDA Medwatch number.

As written, the Rule will cause enormous confusion to consumers of OTC drugs for several reasons. In order to comply with the OTC drug facts label requirements, FDA is proposing to incorporate the side effects statement by amending 21 CFR 201.66 (c)(5)(vii). The proposed rule directs consumers to **“Stop use and ask a doctor if: [Bullet] side effects occur. You may report side effects to FDA at 1-800-FDA-1088.”** It is unclear what “side effects” a consumer should report. Is a “side effect” something that is anticipated and listed as an adverse event on the label, or is it a subjective determination made by the consumer? If it is the latter, it could be an adverse event that is unrelated to the product itself.

Because the 1-800 number is to be used only for the purpose of reporting adverse events, the consumer should not call the number to obtain medical advice. However, in the event of a serious adverse reaction, some consumers may resort to the 1-800 number for guidance and direction. This is a predictable and inevitable result, given the fact that the required labeling statement excludes language to clarify that a patient should not call the number to obtain medical advice. An unqualified directive to phone FDA may be taken quite literally by some consumers and possibly dangerously by someone in a medical emergency.

Furthermore, many OTC drugs already list a 1-800 number on their labeling. It is well known that consumers call company 1-800 numbers for responses to and redress for any and all problems, complaints and concerns associated with their use of the product. The manufacturer's 1-800 number can be a useful source for product monitoring and potential adverse experience problems. Listing the 1-800 Medwatch number could potentially dilute a company's tracking of truly serious adverse events and hinder their receipt.

C. Implementation of the Rule will waste valuable Agency resources

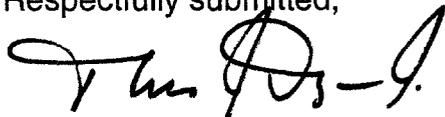
This proposal will also impose significant strains on the Agency's limited resources. Specifically, the Rule will overwhelm limited Agency resources at the Medwatch program. FDA's reliance on listing the Medwatch number on OTC products approved under section 505 is misguided and erroneous. As previously stated consumers will contact the Agency for many reasons, several of which will be unrelated to detecting adverse events.

Furthermore, drugs approved under section 505 are already subject to mandatory adverse experience reporting, so the inclusion of the 1-800 number is duplicative and unnecessary.

D. Conclusion

For these reasons CTFA urges FDA to revise the Rule to exclude all OTC drugs approved under section 505. Application of the Rule to these products appears inconsistent with the statutory language and history of the BPCA. Coverage of OTC drugs will be confusing to consumers and manufacturers alike, and an unnecessary burden on the Agency's limited resources.

Respectfully submitted,



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cc; Charles J. Ganley (HFD-560)