C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

June 12, 2003

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane, Room 1061
Rockville, MD 20852

Re: Bar Code Label Requirement for Human Drug Products and Blood; Proposed Rule; Docket No. 02N-0204

Dear Sir or Madam:

These comments are submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA")[1] in response to FDA's proposed new rule "Bar Code Label Requirement for Human Drug Products and Blood." (68 Fed. Reg. 12500 [March 14, 2003] (hereafter "Rule").

In the Federal Register of March 14, 2003, the Food and Drug Administration (FDA) proposed a new rule that would require certain human drug product labels and biological product labels to have bar codes. FDA explained that the proposed Rule would help reduce the number of medication errors in hospital and health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the correct dose and route of administration) was given to the right patient at the right time. The bar code for human drugs would be required to contain the National Drug Code (NDC) number in a linear bar code format.

CTFA members include manufacturers and distributors of traditional OTC drugs as well as products that are traditionally cosmetics but also provide important drug benefits ("cosmetic-drugs"), such as skin care products with sunscreen. Such products include skin protectants, topical antimicrobials, antidandruff shampoos, antiperspirants, sunscreens, and fluoride toothpaste and mouthwashes, all of which provide valuable health benefits to consumers.

[1] CTFA is the national trade association representing the personal care product industry. Founded in 1894, CTFA represents almost 600 companies involved in the sale or distribution of cosmetics, toiletries, fragrances and OTC drugs throughout the world. Approximately one-half of CTFA's members are manufacturers or distributors of finished personal care products. The other one-half are suppliers of goods or services to those manufacturers or distributors.

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CTFA supports FDA's goal of reducing the number of medication errors by improving the ability of hospital and health care personnel to properly dispense and administer medications. However, we strongly believe that this proposal does not adequately distinguish between the OTC drug products that FDA asserts raise the safety concerns addressed in the preamble to its proposed Rule and those cosmetic-drug products which do not present these concerns. As discussed below, we believe the Rule should be written to specifically exempt cosmetic-drug products that are not subject to dosage limitations.

In addition, we believe FDA should not require the UPC codes of non-dosage OTC drug products to include NDC numbers. Lastly, we urge FDA to not require lot numbers and expiration dates in a UPC code.

A. FDA Should Exempt OTC Drugs with No Dosage Limitations from the Bar Code Label Requirements

As the Agency rightfully recognizes, not all OTC drug products are alike. The FDA proposal states that,

> Proposed Sec. 201.25(b) would also include the phrase "dispensed pursuant to an order" with regard to OTC drugs. Some products in hospitals that are traditional types of OTC drugs, such as aspirin or acetominophen, are dispensed pursuant to a physician's order. Other products that are regulated as OTC drugs are not dispensed pursuant to a physician's order. *For example, a hospital might provide fluoride toothpaste or mouth rinses to a patient without a physician's order. Because these products are not likely to contribute to medication errors, the proposal would focus only on those OTC drugs used in hospitals that are dispensed pursuant to an order.*
> (68 Fed. Reg. 12500, 12506, emphasis added)

Unfortunately, the Rule as written does not adequately distinguish between the types of OTC drug products that the Agency envisions might contribute to medication errors and the types of OTC drug products that would not. For the reasons set forth below, the distinction between drugs covered by this regulation and those which are not should be based on OTC drug products with dosage limitations versus non-dosage OTC drug products, rather than whether a product is dispensed under an order and commonly used in hospitals.

CTFA believes that the proposed Rule a drafted could be interpreted inappropriately, and perhaps unintentionally, to include a broad category of cosmetic-drug products (i.e., those cosmetic-drugs that bear no dosage limitation) that should be exempt from the proposed bar coding regulation.

In previous submissions CTFA has proposed to define "dosage limitation" as follows:[2]

> "a set of limitations on the size, frequency, and number of doses required in the labeling of a product marketed either pursuant to a Tentative Final Monograph, where applicable, or Final Monograph for an OTC Drug Product Category or a specific New Drug Application approval."

CTFA requests that the Rule specifically exempt non-dosage OTC drug products. Products within this category would include, but are not necessarily limited to: (1) antidandruff shampoos, (2) antiperspirant/deodorants, (3) skin protectants, (4) instant hand sanitizers and antimicrobial soaps (health care antiseptic drug products), (5) sunscreens, and (6) fluoride toothpaste and mouthwash products.

This request is appropriate in terms of the inherently wide margin of safety between effective dose and a toxic dose that is associated with the use of these products. The enumerated medication errors that FDA is trying to avoid by proposing the Rule are based on errors of dosage. With the exception of some allergic reactions, none of the Agency's bases for concern, as stated below, are relevant to non-dosage OTC drug products:

- Administering the wrong dose to a patient;
- Administering a drug to a patient who is known to be allergic;
- Administering the wrong drug to a patient or administering a drug to the wrong patient;
- Administering the drug incorrectly;
- Administering the drug at the wrong time; and
- Missing or duplicating doses.

B. FDA Should Incorporate Language that Specifically Exempts Non-dosage Drugs from the Requirements of Proposed Section 201.25

The terminology of the proposed Rule to describe OTC drugs that should be subject to the bar code requirement ("...over-the-counter drug products that are dispensed under an order and are commonly used in hospitals" which is further defined as "packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals,") does not sufficiently distinguish

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[2] See comments by The Cosmetic, Toiletry, and Fragrance Association on FDA's Proposed Regulations on Over-The-Counter Drug Labeling, 62 Fed. Reg. 9024 (February 27, 1997) dated October 6, 1997, p. 3.

between those OTC drugs that are likely to be involved in medication errors from those that are not, i.e. non-dosage OTC drug products.

Non-dosage OTC drug products are routinely dispensed in hospital settings in a manner that could be interpreted as "pursuant to an order." Examples include skin protectants in neonatal units, sunscreens for patients in hospital treatment programs, as well as instant hand sanitizers and other topical antimicrobials throughout the health care system. The practice of dispensing these OTC drug products is not based on "risk" to patient, but rather to ensure that all products – OTC drugs, and otherwise – are captured in hospital and health care billing systems. In addition, dispensing records help ensure that products are dispensed according to the hospital formulary which lists approved drugs for various therapeutic areas, including those that non-dosage OTC drugs are intended to treat or prevent in the hospital or health care setting.

Most manufacturers of non-dosage OTC drug products do not use different labels for the hospital versus private consumer setting. In fact, manufacturers are often unaware that their product lines are being sold through drug purchasing contracts or catalogues. Therefore, FDA's assumption that the manufacturer would know that an OTC drug product may be sold to a hospital or other health care facility and therefore subject to the bar coding requirement is incorrect.

For these reasons we request that the language of proposed Section 201.25 specifically exempt non-dosage OTC drug products. In the alternative, we would ask that the Agency explicitly clarify that the language of drug products "dispensed under an order and ... commonly used in hospitals" is <u>not</u> intended to include non-dosage OTC drug products including, but not limited to skin protectants, instant hand sanitizers and other topical antimicrobials, antidandruff shampoos, antiperspirants, sunscreens, fluoride toothpaste and mouthwash products and other non-dosage OTC drug products.

C. FDA Should Not Require that the UPC Codes of Non-dosage OTC Drug Products Include NDC Numbers

FDA's proposal to require that UPC codes include NDC numbers would unfairly impact non-dosage OTC drug products. It would be a burdensome regulation with little benefit or foundation for the cost of imposing it. As FDA recognizes in the proposed Rule, the OTC drug industry has an established tradition of using UPC codes, many of which do not contain NDC numbers. This system has worked well to ensure efficiency and coordination between manufacturers and retailers. It has provided the industry with maximum flexibility to assign unique identifying numbers to different shelf-keeping units (SKUs) and afforded retailers an efficient means to distribute OTC drug products throughout the retail sector. This requirement would disrupt the industry and retail channels of trade that rely on UPC codes to oversee commercial distribution.

This proposal will also impose significant strains on the Agency's limited resources. Manufacturers would require new and additional NDC numbers for OTC drug product extensions and/or new packaging. FDA would be under additional pressure to provide this information on a timely basis. Currently, Section 201.2 of the regulations "requests" all drug labels to have an NDC label, but it is not a requirement.

This proposed requirement would be even more burdensome for traditional cosmetic-drug product lines that offer a variety of SKUs in response to consumer demands for cosmetic, as well as OTC attributes in non-dosage OTC drug products. For example, a makeup or lipstick product with sunscreen may be offered in many different colors. In such cases, changing UPC codes to include the NDC will have a major adverse impact on retailers and manufacturers.

D. Required Use of NDC Will Result in Unnecessary Expenses for Manufacturers and Logistical Complications for Retailers

If the NDC is required to be incorporated in the UPC, manufacturers will incur thousands of dollars in unnecessary extra "new item" costs. A different NDC is required for even minor formula modifications whereas changes in active or inactive ingredients in OTC formulations currently do not require a change in the UPC. In the latter situations, different suffixes and lot numbers are used for control purposes to differentiate between product formulations, but the basic UPC does not change.

A requirement that a manufacturer have a new NDC and therefore a new UPC for every minor change in an OTC drug product forces retailers to regard the product as a new item which has very significant logistical and financial

consequences. Retailers must re-code warehouse, shelf code and other control systems for each new item, and manufacturers will be charged substantial fees to cover the cost of this activity. These fees are called by various names such as new item fees, maintenance fees, and set-up fees.

As a result, we believe the Agency inadvertently has set the stage for a very significant and expensive logistical problem. The resulting costs and disruption are clearly not justified by any commensurate benefit in the case of non-dosage OTC drugs.

E. FDA Should Not Require Lot Numbers and Expiration Dates in a Bar Coded NDC Number.

Non-dosage OTC drug products are not currently required to bear expiration dates so long as they meet the appropriate stability testing requirements. There is an existing exception to OTC drug expiration dating for non-dosage OTC drug products. According to Section 211.137 of the regulations, FDA does not require expiration date listing for OTC drugs if 1) the labeling does not bear dosage limitations, and 2) they are "stable for at least three years as supported by appropriate stability data." Therefore, this information should not be required to be included in bar codes.

In addition, requiring lot numbers in the UPC will also impose an unnecessary burden. (The lot codes are otherwise available on the label if necessary.) Including this information in the bar code will, in most cases, require new production line equipment to apply the UPC at a later stage of the production process. This additional requirement imposes substantial additional costs on the industry and consumers, and provides no additional benefit to consumers and patients.

F. Conclusion

While CTFA supports the Agency's stated objective to reduce medication errors, we believe that imposition of bar code labeling for OTC drug products without dosage limitations is burdensome, disruptive to the industry, and unnecessarily costly to consumers and manufacturers alike.

We appreciate the opportunity to provide these comments. Please feel free to contact us if you have questions or need additional information.

Respectfully submitted,

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