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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

January 31, 2000

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

E. EDWARD KAVANAUGH
PRESIDENT

Re: Draft Guidance for Industry, "Labeling of Over-the-Counter Human Drug Products Using a Column Format"

These comments are submitted on behalf of the members of The Cosmetic, Toiletry, and Fragrance Association ("CTFA") in response to the agency's draft guidance for industry on the use of columns as part of the standardized format and content requirements of the final OTC labeling rule. CTFA membership includes approximately 300 active member companies that manufacture or distribute personal care products, including many that provide both cosmetic and drug functions in the same product ("cosmetic-drugs"). CTFA also represents approximately 300 additional associate members who provide goods and services to manufacturers and distributors of personal care products.

The final OTC labeling rule does not provide adequate justification for its application to cosmetic-drug products with no dosage limitations, nor does it provide realistic labeling options for the myriad variety of small packages for OTC drug products.

For those products that are appropriately subject to the rule, CTFA has always supported the use of columns in the OTC labeling rule to accommodate the variety of existing (as well as future) OTC package sizes. While such accommodation will not resolve our fundamental problems with the rule as written, it will provide important relief in the form of increased flexibility in implementing the Final Rule to ensure that consumers read and understand drug facts labeling. Our comments to specific features of the draft Guidance Document follow.

Columns Under the Standard Labeling Format

We urge FDA to provide maximum flexibility in the use of columns to allow manufacturers to comply with the requirements of the final OTC labeling rule. Specifically, we believe FDA should permit the use of columns in two ways: (1) columns *within* a single Drug Facts box and (2) columns *to place adjacent Drug Facts boxes on one or more panels*.

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In situations other than active ingredient/purpose and complex dosing information, the guidance document specifies that required drug facts information may not be separated into columns within a Drug Facts box. This limitation is unreasonable and has not been adequately justified by the agency in its basis for the rule.

CTFA supports the agency's position to allow for the use of two or more Drug Facts boxes on the same side of the outer package. Consumers are not only used to reading complex information in a multiple-column format, but rely on it to process a wide variety of data (e.g. *Federal Register*, telephone books, newspapers). We nevertheless urge the agency to remove some of the limitations which it has imposed when using multiple columns on a panel. For example, the requirement that multiple columns should be approximately the same size should be eliminated. Manufacturers may find it more suitable to present the drug facts information in two or more columns of different widths. This accommodation would allow for the use of pictures/diagrams within the box, as well as provide more flexibility for manufacturers in locating other labeling such as required labeling information for cosmetics and UPC codes.

In addition, we strongly urge the agency to eliminate the "Drug Facts (continued)" requirement from the top of the second (and additional) Drug Facts boxes on the same panel. This requirements is repetitive, adds no value to the consumer's comprehension of what he or she is reading, and takes valuable space for required labeling. Likewise, we consider the use of an arrow to be unnecessary.

We urge the agency to allow maximum flexibility in both the number and width of columns, so long as the Drug Facts information is consistent with the form and content requirements of the Final Rule. Furthermore, we urge your consideration of reasonable flexibility in the use of columns on more than one panel, i.e. that a manufacturer be permitted to use columns on multiple panels in such a fashion that one panel may have two or more columns, and the next panel may use only one column if necessary to implement the Final Rule.

Columns Under the Modified Labeling Format

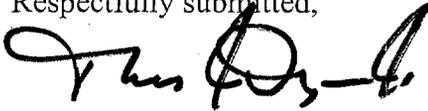
In previous comments to the agency, we have stated that the Modified Labeling Format is of limited value in accommodating the Drug Facts labeling information on smaller packages. Nevertheless it provides some relief from the Final Rule which does not currently address the labeling limitations of several small OTC packages. The provision to allow for columns in the modified format is helpful, but we request the agency to allow for separation of the columns by a vertical line, as another alternative, to the current option of using a contrasting color. The guidance document currently provides an option to share a common vertical barline extending to each end of the Drug Facts area when using two or more Drug Facts boxes on the same side of a package. We recommend that this option also be permitted for labeling under the modified labeling format.

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Conclusion

In conclusion, the draft guidance for using a column format when labeling OTC drug products is a welcome first step. Although this step by itself would not make compliance with the regulation feasible or even appropriate for many cosmetic-drug products, we hope that it signals the Agency's willingness to address the long list of problems posed by this rule in the near future.

Respectfully submitted,



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