



July 2, 2002

Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Over-the Counter Drugs; Labeling Requirements; Partial Stay of Compliance [Dockets nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

To whom it may concern:

Pfizer Consumer Healthcare submits comments in response to FDA's April 5, 2002, *Federal Register* publication of a partial stay in compliance for certain products which are subject to FDA's final rule that established standardized format and content requirements for the labeling of all OTC drug products (Drug Facts Rule). These products are designated in the partial stay of compliance as "convenience size" over-the-counter (OTC) drug products.

The matter of defining what OTC drug products qualify as a "convenience size" package is a difficult matter and careful consideration in reviewing the comments from various manufacturers, repackers and distributors should be taken before the agency makes a final decision. Therefore, Pfizer Consumer Healthcare submits the following comments:

- Further consideration of the "1 to 2 dose" criteria needs to be undertaken. Rather than being defined as simply "1 to 2 doses", the criteria should be defined by the number of doses, which would provide temporary relief for one day. Thus, for a product which is directed to be taken once in a 24-hour period, the convenience size would be one dose. For a 12-hour product, the convenience size would be 2 doses. For a 6-hour product, the convenience size would be 4 doses. Another example is a single roll of antacid tablets, such as Roloids®, which contain a single day's supply of antacid when taken in accordance with the labeled directions. We would suggest that the limit allowed by a convenience size would be four doses. Unless FDA can find a legal justification or public health justification for the "1 to 2 dose criteria" for a short acting product (i.e. 6-hours or less), we suggest that the 4 dose limitation may be a valid and economic option for both manufacturers and consumers.

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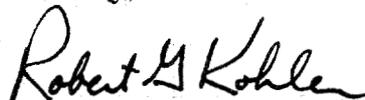
- The definition of “convenience size” should be sufficiently broad to include all non-recloseable oral or topical drug products regardless of whether a consumer would use the product sparingly and thereby have multiple doses or whether a consumer would use the entire amount supplied at one interval.
- Manufacturers with products which meet the convenience size definition may still elect to follow some of the provisions of the Drug Facts rule to keep consistency in the presentation of information across the sample, convenience and retail sizes of the same product. This may be accomplished for the sample or convenience sizes by utilizing a decreased type size, allowing wrapping of bulleted statements (i.e. a paragraph format) and the removal of the hairlines and bar lines between sections of information. FDA, by regulation, should allow these changes as long as the content of the labeling conforms to the labeling permitted in the appropriate monograph(s).

Accordingly, Pfizer Consumer Healthcare requests that FDA consider the above comments in implementing the partial delay of compliance and in preparing a proposed rule regarding labeling of OTC “convenience size” packages.

Pfizer Consumer Healthcare appreciates this opportunity to submit comments to the partial stay in compliance published by the Agency. We would be willing to meet with FDA to further discuss the above points. In addition, we would be willing to prepare and submit relevant examples of labeling to further illustrate the above points.

If you have any questions or need additional information, please contact me at (973)-385-5419.

Sincerely,



Robert Kohler
Regulatory Consultant