

SB
SmithKline Beecham
Consumer Healthcare

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January 28, 2000

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

Docket No. 99D-5013

**Re: Draft Guidance for Industry "Labeling OTC Human Drug
Products Using a Column Format" (November 1999)**

Dear Sir/Madam:

SmithKline Beecham Consumer Healthcare submits these comments in response to the publication of FDA's Draft Guidance for Industry on the use of columns as part of the standardized format and content requirements of the final OTC labeling rule. SmithKline Beecham Consumer Healthcare (SB) supports the agency's goal to enable consumers to better read and understand OTC drug product labeling and appreciates the opportunity to comment on this guidance.

SB 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 used to reading information in a multiple-column format such as magazines and newspapers. SB however urges the agency to remove some of the limitations that 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. There is no readability benefit to having columns of equal width and based on the particular copy that is required, there could even be an advantage to using columns of unequal width.

SB urges the agency to eliminate the "Drug Facts (continued)" requirement from the top of the second and subsequent Drug Facts boxes on the same panel. This requirement is repetitive, adds no value to the consumer's comprehension of what he or she is reading and takes valuable space for required labeling. In addition, SB

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considers the use of an arrow to be unnecessary since consumers are accustomed to reading in this manner.

SB recommends that manufacturers be allowed to start a heading or a subheading on one column and continue on to the next column by repeating the previous heading or subheading and adding "continued" in parenthesis. This would replace the need for Drug Facts (continued) but still indicate the flow of the text to the consumer.

SB hopes that the agency will find these comments useful and will incorporate them into the final guidance document. The use of columns will not resolve all of the fundamental problems with the rule as written, but 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.

Sincerely,



Anthony Amitrano
Associate Director
Regulatory Affairs



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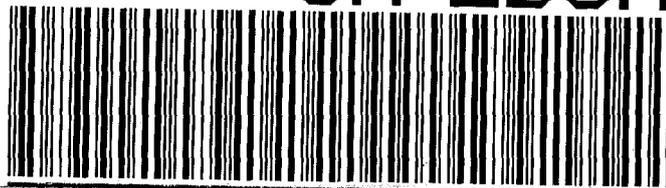
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