



Bristol-Myers Squibb Company

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August 2, 2005

**Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852**

Re: Docket No. 2005D-0202; Draft Guidance, *Draft Guidance for Industry on Bar Code Label Requirements-- Questions and Answers, 70 Federal Register 33182 (June 7, 2005)*

Dear Sir or Madam:

Bristol-Myers Squibb (BMS), a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, infant formulas, and nutritional products, is pleased to have the opportunity to offer comments on the draft guidance referenced above. BMS' mission is to extend and enhance human life by providing the highest-quality pharmaceutical and related health care products. For this reason, we are interested in commenting on the draft guidance. Our comments are set forth below.

Summary of BMS Comments on Draft Guidance

We commend the U.S. Food and Drug Administration (FDA) for providing additional guidance on the bar code label requirements. There is, however, one aspect of the draft guidance that is still unclear and requires additional clarification, which we have cited below.

Specific Comments (Items that Need Clarification & Recommended Actions)

The FDA Bar Code Label Requirements for Human Drug Products and Biological Products, 69 Federal Register 9120 (February 26, 2004) call for compliance by April 26, 2006. BMS is committed to complying with this regulation by April 26, 2006, but wanted to call the FDA's attention to an ambiguity in the regulation.

The current version of the regulation is unclear as to whether product packaged without NDC bar codes prior to April 26, 2006 could be sold *or* if such non-NDC labeled product would need to be relabeled prior to being sold. The latter scenario would require all product shipped after April 26, 2006 to have compliant NDC bar codes, which would require BMS to destroy existing inventories (within BMS' control and at third party distributors), and which could ultimately result in stock outs for certain products.

FDA could help prevent the need for destruction of certain product inventories, as well as the potential backorder situation this could cause by defining the compliance date for packaging of new materials.

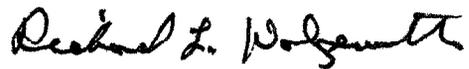
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Recommendation: FDA should consider clearly defining compliance with the Bar Code Label Requirements as all products packaged on or after April 26, 2006 must incorporate a compliant bar code.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Regards,



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