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July 11, 2001

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: FDA Draft Guidance for Industry - Forms for Registration of Producers of Drugs and listing of Drugs in Commercial Distribution (Docket No. 01D-0192), [66 Federal Register 26867 (May 15, 2001)]

Dear Sir:

Bristol-Myers Squibb is a diversified global health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, as well as neurological disorders and oncology. In 2000 alone, Bristol-Myers Squibb dedicated more than $1.8 billion to pharmaceutical research and development activities. The company's more than 4,300 scientists are committed to discovering and developing best-in-class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development. For these reasons, we are very interested in and well qualified to comment on this FDA proposal to revise the procedures for drug and establishment listing.

We commend the FDA for moving forward to develop processes that will facilitate eventual electronic submission of establishment registration and drug product listing.

Summary of BMS Comments on Proposal

There are several aspects of the proposed guidance that appear to hamper the apparent objectives of streamlining the workflow for the Agency and the individual sponsors, and enhancing the accessibility of drug listing information to the public. These issues are cited below.

Specific Comments

01D-0192 C4

I. Elements Which Should Be Modified

(A) Elimination of Form 2656e

The Agency proposes elimination of the annual mailing of Form 2656e for re-registration of a facility, unless specifically requested, and will require that such updates of an establishment registration be provided instead on Form 2656.

Since the majority of those who would be using Form 2656 will, in fact, be re-registering rather than registering an establishment for the first time, the Reason for Submission field in most forms will include the written entries, ANNUAL or ANNUAL-NO CHANGES.

Recommendation: FDA should consider modifying form 2656 to permit more efficient entry of the required information. An additional check box for ANNUAL would suffice, since any changed information would be indicated on the form. To confirm those cases where no changes are made, an ANNUAL-NO CHANGES box could also be added.

(B) Elimination of the Routine Mailing of the CVR.

The Agency proposes the elimination of the annual mailing of the Compliance Verification Report (CVR), and suggests that sponsors use the National Drug Code Directory available on the Internet.

The routine annual review of the CVR provides a useful check both on the accuracy of the National Drug Code Directory, and the completeness of an individual company's listing for a given labeler code. The CVR also provides detailed information in a relatively compact and convenient format. The National Drug Code Directory now available on the FDA web site presents only a limited number of fields for each entry. Thus it is less well suited than the CVR for permitting the sponsor to verify the full contents of a specific drug listing.

Recommendation: If the routine distribution of the CVR is eliminated, options should be made available to provide broader access to the information previously submitted by the sponsor. The guidance should indicate that sponsors could still request a full Drug Listing for each labeler code from the Drug Listing Branch. Alternatively, they could be given the option of retrieving a more detailed listing for a labeler code than is currently available from the FDA web site.

II. Elements Which Should Be Clarified

(A) Simplification of the Process for Updating of Drug Listing Information

The proposed guidance indicates that the updating of information on Form 2657 or 2658 would be satisfied by completion of only those sections of the relevant form that are affected by the change

Current regulations (and instructions) call for the initial drug listing for a product to include a representative sampling of labeling. The instructions for providing information about changes in a drug listing do not specifically request the sponsor to provide updated labeling. The guidance should clarify whether updated labeling needs to be routinely submitted with any Form 2657 that reports only changes in labeling information.

Bristol-Myers Squibb appreciates this opportunity to provide comments on the draft guidance and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional information that may be requested.

Sincerely,

Laurie Smaldone, M.D.
Sr. Vice-President
Regulatory Science and Outcomes Research

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