

December 7, 1999

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Docket Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 99D-2873  
Draft Guidance on Evidence Models for the Least Burdensome Means to Market

Dear Sir or Madam:

Bayer Diagnostics is writing to express its support of the comments submitted to FDA by the Least Burdensome Task Force on the "Draft Guidance on Evidence Models for the Least Burdensome Means to Market." These comprehensive comments are consistent with the positions of the diagnostic industry in general, and Bayer Diagnostics, specifically.

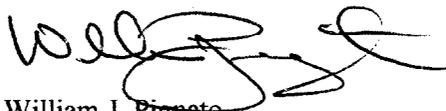
We recognize that the draft guidance is an important step in enacting the requirements of FDAMA, which requires consideration of the "least burdensome" approach in device approvals and clearance. Like the Task Force, we feel that FDA's proposal is too narrow in scope in that it focuses solely on clinical trial requirements and excludes in vitro diagnostic devices. We do not agree with FDA's position on the exclusion of IVDs due to their "unique clinical data needs..." and support the recommendation that the draft guidance be revised to be inclusive for all categories and classes of devices, including IVDs.

The proposed guidance has not addressed the scope of the statute by failing to apply it to all types of devices, including those subject to 510(k) clearance. As FDA has noted in the draft guidance, 510(k) submissions that require clinical data are the exception rather than the rule. A more effective and useful guidance document must also address "least burdensome" issues that are not limited to Premarket submissions requiring clinical data.

We support the Task Forces' recommendations for a more interactive process in the development of a revised guidance. This process has been very effective in developing and responding to such regulatory initiatives as the Product Development Protocol and the guidance documents for PMA Supplements and 510(k) modifications. Therefore, we support the specific recommendation of the Task Force to form a "least burdensome" working group composed of FDA and industry representatives to review the current proposal and develop the necessary revisions.

We appreciate the opportunity to provide comments on the subject guidance.

Sincerely,



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