

July 1, 2004

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

FDA Docket No. 2004D-0187, 2004D-0188, and 2004D-0189

Three Draft Guidances for Industry entitled Premarketing Risk Assessment; Development & Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices & Pharmacoepidemiologic Assessment

Dear Sir/Madam:

As a leader in the discovery, development, manufacture and marketing of prescription medicines, Johnson & Johnson pharmaceutical business and research organizations are committed to improving health and well being through innovative products and services. We share the Agency's goal of bringing safer and more effective drugs to the market as rapidly as possible. We embrace the importance of risk management, and are pleased to have the opportunity to comment on the FDA's Draft Guidance of May 5, 2004, entitled, "Premarketing Risk Assessment, Development & Use of Risk Minimization Action, and Good Pharmacovigilance Practices & Pharmacoepidemiologic Assessment." I am sending these comments on behalf of the Johnson and Johnson pharmaceutical business and research organizations.

We agree with FDA that the ultimate goal of risk management is to ensure that efforts and costs involved in risk management efforts are expended on effective processes that achieve a positive benefit/risk balance for patients. With proper use, drugs can provide enormous benefit to patients and can reduce overall healthcare costs.

We have several broad comments to make about the overall risk management concept. This general feedback is found below. More specific comments as they pertain to each draft guidance can be found in the subsequent *attachments*.

- While the proposed guidances acknowledge that even large clinical development programs cannot reasonably be expected to identify all risks associated with a product, J&J is concerned that the FDA may attempt to require large numbers of additional studies to identify as many risks as possible prior to approval. Such an approach may result in significant delays in drug development.
- Consistent standards must be used across all Divisions so that decisions about individual drug products are not made on different criteria based on a particular reviewer's views. We

recommend that a high level review committee within the FDA be constituted to ensure that decisions regarding risk management that affect drug development programs and the need for RiskMAPs are made appropriately and consistently.

- Our hope is that any assessment and decision about risk management interventions would be based on the benefits as well as the demonstrated risk profile of the drug product. We believe that risk management programs/ interventions should balance access of patients to needed drugs with the level of concern. We were very pleased to see reference to the balancing of benefit to risk throughout the documents and also an acknowledgement that risk minimization plans should be used judiciously so as not to interfere with the delivery of benefit to the patient.
- We were also pleased to see that for most products, the FDA feels that routine risk minimization measures are sufficient. While that was stated in the original concept papers, it was made very clear in the proposed guidances that requirements for Risk MAPs will be the exception rather than the rule at the FDA and we agree with that approach.
- Collaboration between the FDA and industry on the development and approval of RiskMAPs and pharmacovigilance plans is critical. We were pleased to see that the FDA recommends many interactions with industry to discuss safety as drug development proceeds. Again, it will be critical for the FDA to ensure that safety issues are evaluated as consistently as possible across Divisions and that there is a great deal of oversight regarding the decisions to require additional studies or a RiskMAP and the selection of tools which must be employed.
- Clearly, there are a number of stakeholders who must also collaborate with FDA and industry, including academic institutions, healthcare providers, third party payers, pharmacists, professional societies, and patient groups, if significant improvement in overall benefit/risk balance for patients is to be achieved. It was very welcome to see the FDA embrace this concept across the proposed guidances.
- Finally, Johnson & Johnson applauds the FDA's efforts to conform to harmonized international definitions and standards as much as possible. It is very difficult for industry to develop drugs efficiently if the health authorities use different approaches, definitions and standards.

In closing, we appreciate the opportunity to comment on these important draft guidances and look forward to working with FDA to ensure the safe and effective use of all prescription drug products.

Sincerely,

A handwritten signature in black ink, appearing to read "Janice K. Bush". The signature is fluid and cursive, with a large initial "J" and "B".

Janice K. Bush, M.D., Vice President

*Liaison, Quality Management and Business Support*

**Johnson & Johnson Pharmaceutical Research & Development  
Benefit-Risk Management**

Attachments (#3)