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

October 14, 2003

FDA Docket No. 00N-1484
Safety Reporting Requirements for Human Drug and Biologic Products

Dear Sir/Madam:

As leaders in the discovery, development, manufacturing and marketing of prescription medicines, the pharmaceutical business and research organizations in the J&J family of companies are committed to improving health and well being through innovative products and services. I am sending these comments on their behalf.

We fully support the FDA's goal of "protecting and promoting public health" by way of amending its safety reporting regulations. We believe that increased quality of safety reports will benefit the patient and consumers, and applaud the initiative to strengthen our safety reporting system. We are pleased to have the opportunity to comment on the FDA's Draft Proposed Rule on Safety Reporting Requirements for Human Drug and Biologic Products. We have several broad comments to make about the overall safety reporting requirements proposal. This general feedback is found below. More specific comments and recommendations as they pertain to the various sections of the draft proposed rule is included in the enclosed attachment.

Although we believe that increased quality of safety reports will benefit the patient and consumers, we are concerned that an initiative whose intention is to "eliminate unnecessary reporting burdens on industry so that companies can focus on the safety profiles of their products" is, in fact, going to have the opposite effect. Due to the additional types of new reports required and increased reporting due to the lowered threshold on the clinical trial reports, it is likely that the system will be flooded with additional Adverse Event (AE) reports, many of which will create "noise" and will obscure true signals. Companies will be focusing attention on complying with all the new regulations and requirements associated with the new reporting requirements, but it may be that the actual surveillance will not be improved since the ability to distinguish real safety risks will be obscured by artifacts in the system. This seems at odds with the FDA's recently touted strategic goal of efficient, science-based risk management.

We believe that the resources required to meet the currently proposed regulations will be vastly more than those predicted by FDA. In particular, we are concerned that there will

be a greatly increased need for very specialized staff in an environment where such resources are already scarce. In addition to the intensive re-training of current staff, new staff will need to be recruited and trained at the same time that every other company is competing for the same scarce resources. We believe this huge resource increase that will be required is real and should be acknowledged.

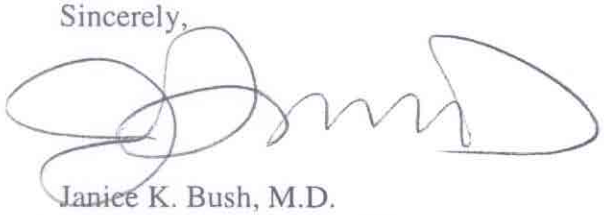
Due to the need to develop the human resources as well as additional infrastructure at our company, we suggest that an extended timeframe is appropriate for implementation once the Final Rule is published. We request that the FDA set a date for implementation 18 months after the Final Rule is published in the Federal Register, to allow time to comply with all of the new safety reporting requirements.

Another concern of ours is the "backseat" that medical judgment is taking in the proposed process. Although the FDA is requesting that licensed physicians review cases and be listed on every submitted report, the FDA is also suggesting, by the proposed new definition/interpretation of "SADR", that physicians are not capable of assessing causal relationships in investigational drugs. Instead, the proposed rule sets up a paradigm whereby virtually all the clinical trial events will be classified as "related". The FDA also appears to be dismissing medical judgment by requiring reporting of certain labeled events to always be expedited. We are concerned by this change of approach and think that the under-valuation of medical judgment will also make assessment of true signals more difficult.

Finally, we commend the FDA for attempting to clarify definitions and requirements and to bring its regulations into worldwide harmonization. Nevertheless, we see many areas where the FDA is proposing changes not in keeping with ICH guidelines, CIOMS proposals or with other regulatory bodies worldwide. Requiring new activities that are specific only to the US, and especially those that are in conflict with the rest of the world, will clearly produce additional burdens for global companies. Instead of having a positive outcome of increased clarity, there will be the potential for confusion and non-compliance.

In closing, we appreciate the opportunity to comment on this important new proposal and look forward to working with FDA to ensure the safe and effective use of all prescription drug products and over the counter drug products.

Sincerely,



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Attachment (1)