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

RE: Risk Management -- Premarketing Risk Assessment -- Docket No. 02N-0528

Dear Sir or Madam:

On behalf of the Pharmaceutical Printed Literature Association (PPLA), I am writing with regard to the request for comments on Premarketing Risk Assessment published by the U.S. Food and Drug Administration as FDA Docket Number 02N-0528. Specifically, the PPLA applauds FDA for initiating efforts to improve risk management at all phases of a drug product's lifecycle, and the Agency's efforts to implement good risk assessment practices during product development. The PPLA also endorses FDA recommendations presented in the Concept Paper entitled *Premarketing Risk Assessment*, released by FDA on March 3, 2003.

As outlined in these comments, however, the PPLA maintains that enhancements should be made to:

- Section III, "Important Considerations in Generating Risk Information During Clinical Trials;" and
- Part F, "How can sponsors minimize medication errors?"

PPLA Background

The PPLA is a not-for-profit association chartered in 2001 to serve as the voice of pharmaceutical printed package information manufacturers, and provide a forum for members to promote and improve delivery of information for protection of patients. To do so, the PPLA works to support health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. Additionally, PPLA acts as an educational resource for strategic partners and the public.

As a young association, PPLA's core initial goal is to help the pharmaceutical industry help consumers benefit from existing and new drugs - a return on investment of billions of research and development dollars - by taking those drugs as prescribed, with instructions, precautions and risk data clearly understood. The desired outcome is a win-win-win situation: consumers enjoy better health, the healthcare system operates at lower total cost, and drug manufacturers report higher sales.

As a result of the evolution of the Food, Drug and Cosmetic Act of 1938, the carefully-regulated content of printed literature provided by pharmaceutical manufacturers has been the primary means for communicating to physicians and pharmacists how and when patients should take drugs correctly, and how to avoid mistakes. But despite this history, there is still no guarantee that patients will get accurate information directly from the manufacturer each time they have a prescription filled. And today, consumers are playing an increasing role in identifying medications and specifically requesting that their doctors write prescriptions for one drug instead of another.

This trend has already caused liability concerns in at lease one state, New Jersey, where the state's supreme court has abolished the "learned intermediary" defense for pharmaceutical manufacturers who engage in DTC advertising. One of the functions of the PPLA, therefore, is to offer input to FDA, Congress, and other governmental agencies on how to provide reliable, detailed and controlled information for healthcare professionals and consumers in the age of direct-to-consumer and Internet information. Our members have extensive expertise in developing inserts, outserts and labeling used by physicians, pharmacists and patients to ensure that drug products are prescribed, dispensed and consumed properly. We stand ready to assist FDA in all efforts to promote wellness through information sharing.

PPLA Comments

The PPLA respectfully submits the following label-specific recommendations to Section III, part F, of the Premarketing Risk Assessment concept paper.

1. The recommendations proposed by FDA (lines 313 through 335), should be adopted immediately and stated explicitly in the Agency's final guidance. Evidence presented to FDA on various occasions by groups including the American Society of Health-System Pharmacists and the Institute for Safe Medication Practices has documented the connection between poor product design and nomenclature on physician inserts, carton labeling and patient product inserts as significant contributors to medication errors and adverse events.

2. The PPLA maintains that premarketing testing, and medication error prevention analysis (MEPA), must be conducted by drug-product sponsors, with any new indications clearly presented as a corrective action in subsequent relabeling or repackaging.

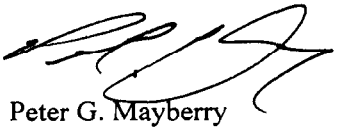
3. To avoid medication errors via "look-alike" and "sound-alike" products, the PPLA urges FDA to establish and explicitly state in the forthcoming guidance that non-proprietary drug manufacturers be held to the same premarketing testing and labeling standards as brand-name drug manufacturers.

4. The PPLA asks FDA to include in its guidance a patient-oriented format for labels that includes trial information such as any titration-relevant indications, interactions indicated relative to over-the-counter products, and identity of look-alike generic products and an advisory statement that indications may differ for the generic product vs. the brand product.

5. The guidance should further state that comprehensive, easy-to-read, and understandable patient package information is deemed the responsibility of drug sponsors, and is central to risk management. FDA guidelines for drug product premarketing should state that all safety-related indications from drug trials must be conveyed in a Medication Guide for all prescription drug products.

The PPLA is pleased to have this opportunity to comment on FDA's risk management initiatives, and further offers its resources as the Agency develops and implements best practices for risk management.

Sincerely,



Peter G. Mayberry
Executive Director