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July 21, 2004

**VIA FACSIMILE: 301-827-6870**

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Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: FDA Docket No. 2003N-0324, "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products"**

Dear FDA:

I am writing on behalf of the Pharmaceutical Printed Literature Association (PPLA) to comment on the proposed rule published by FDA in the April 22, 2004 edition of the *Federal Register*. This proposal (FDA Docket No. 2003N-0324, Regulatory Information No. 0910-AC35) seeks to implement a legislative requirement included in the Best Pharmaceuticals for Children Act (BPCA) such that all human drug products approved under section 505 of 21 USC 355 would be dispensed with FDA's toll-free MedWatch telephone number and a brief statement advising consumers that they can call the FDA number to report side effects from Rx drugs.

While the PPLA recognizes that FDA is acting in response to a specific legislative mandate, we assert that, as proposed, the approach selected by the Agency to implement this requirement will be virtually impossible for the Agency to enforce given its current resources. Simply stated, we disagree with FDA's preliminary decision to place responsibility for complying with these BPCA provisions on the pharmacy industry instead of on pharmaceutical manufacturers.

Indeed, we believe that FDA is missing a rare opportunity to mandate that printed information intended for use by patients be prepared by pharmaceutical manufacturers, approved by the Agency, and dispensed to pharmacies as Rx labeling. As we demonstrated to FDA during its public meeting on July 31, 2003, it is entirely feasible for manufacturers to adhere multiple copies of printed leaflets onto bulk containers of drug products; pharmacy personnel can then remove approved labeling from the bulk container and dispense it with each prescription filled.

Authority for FDA to require that such leaflets be provided by manufacturers has already been granted by Congress under Public Law 104-180, and the PPLA maintains that including the MedWatch toll-free number in approved labeling would be a much more efficient means of complying with Congressional intent spelled out in both the BPCA and Public Law 104-108.

**Background and Comment**

The PPLA is a not-for-profit trade association formed in 2001 by companies that print labeling for pharmaceutical manufacturers and companies that supply these printers. A primary goal of the PPLA is to identify opportunities where printed literature for drug products can be better used to: 1) improve compliance

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with pharmaceutical regimens; 2) reduce risks associated with use of Rx drug products; and 3) improve patient understanding of the drugs which have been prescribed to them. While the PPLA obviously has a vested interest in maximizing the amount of printed literature that accompanies drug products, our association was formed in an effort to improve communications between pharmaceutical manufacturers, physicians, other healthcare providers, and patients.

PPLA members have tremendous knowledge regarding printed materials for Rx drug products, and have repeatedly sought opportunities to share this knowledge with FDA in collaborative efforts to improve the state of approved labeling for patients in the United States. We offer our expertise to FDA here, again, in an effort to ensure that all Rx drugs dispensed in the United States are accompanied by approved labeling prepared by the manufacturer similar to that required in the European Union and other parts of the world.

In the April 22, 2004 *Federal Register* notice, FDA presents several alternatives by which pharmacies can dispense prescription drugs that include the toll-free phone number to FDA's MedWatch center along with a brief statement alerting patients to the fact that they could call this number to report any side effects they experience (but not to seek medical advice). FDA notes that this action is being taken in response to Congressional requirements included in the BPCA.

According to the notice, FDA estimates that 71,730 retail and non-retail pharmacies currently dispense Rx drugs and that, of these, some 19,812 pharmacies would be affected by the proposed rule (FR notice, Table 1). Moreover, FDA estimates that more than 3 billion individual prescriptions are dispensed by pharmacies each year in the United States (FR notice, Table 2).

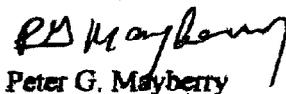
Considering Congressional intent under the BPCA, it is obvious to the PPLA that FDA lacks the resources to ensure compliance with this labeling requirement if the responsibility is placed on dispensing pharmacies. It would be far more efficient, therefore, and much more in keeping with BPCA provisions, if the Agency placed the responsibility with the far more limited number of Rx drug manufacturers that FDA already oversees.

Specifically, we urge FDA to alter the proposed rule such that manufacturers are required to attach sufficient quantities of printed information to bulk containers of Rx drug products to ensure that one piece of approved information – similar to a patient package insert (PPI) or a MedGuide – can be dispensed with each prescription filled from the manufacturers' original container. Rx drug products shipped from the manufacturer in "original packaging" that is not intended to be re-packaged in the pharmacy could be shipped with a single piece of approved labeling.

In either case, the approved labeling could include FDA's toll-free MedWatch phone number as required under the BPCA, as well as other useful patient information outlined by Congress under Public Law 104-180.

On behalf of the Pharmaceutical Printed Literature Association, I thank FDA for the opportunity to comment on this important proposed rule. Should you have any questions or need any additional information, I invite you to contact me via any of the means included in the heading to this letter.

Sincerely,



Peter G. Mayberry  
Executive Director  
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