



August 1, 2002

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

RE: Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format (FDA Docket Number 00N-1652)

I am writing on behalf of the Pharmaceutical Printed Literature Association (PPLA) in response to the notice of proposed rulemaking regarding “Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format” that was published in the May 3, 2002 edition of the *Federal Register* (FDA Docket Number 00N-1652.)

The PPLA is a not-for-profit trade association that was established in 2001 to underscore the importance of printed literature as a means of promoting safe and effective dispensing of drug products, as well as the proper use of drug products by consumers. As FDA well knows, use of printed information has historically played a critical role in ensuring that drug products are dispensed and consumed properly throughout the United States, and a primary objective for the PPLA is to underline the importance of printed literature during this nascent era of electronic communication. For more information on the PPLA, I invite you to visit our website at www.pplaonline.org.

With regard to FDA’s proposed rule, the PPLA has no objection to the use of electronic submissions for New Drug Applications (NDA’s), certain Biological License Applications (BLAs), and/or Abbreviated New Drug Applications (ANDAs). To the extent that such submissions will speed the drug approval process and reduce the potential for errors, in fact, the PPLA applauds FDA for issuing this proposal.

That said, however, the PPLA is tremendously concerned that this proposal – if finalized in its present form – could ultimately serve as the basis for the elimination of printed Patient Inserts (PI’s) as envisioned under the Pharmaceutical Research and Manufacturers of America (PhRMA) “paperless labeling” initiative. Simply stated, PPLA members believe that PhRMA may ultimately advocate use of data that has been submitted to FDA electronically as a substitute for printed PI’s that have been required under Agency regulations for decades.

In case FDA is not aware of this initiative, the PPLA notes that PhRMA established a Paperless Labeling Task Force some two years ago, and site testing of a pilot system is reportedly set to begin this year at several retail pharmacies in the Washington, D.C., area. Should this pilot be deemed a success by the PhRMA Task Force, the PPLA anticipates that a concerted effort will be undertaken by the pharmaceutical manufacturers shortly thereafter to alter current regulations such that printed PI’s would no longer be required.

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Considering the importance of assurances that pharmacy personnel always have access to critical information included on printed PI's – and the numerous potential, long-term problems associated with an electronic substitute for printed PI's (problems ranging from guaranteeing constant, never-ending access to an electronic system for all dispensing sites to more frightening scenarios such as power failures, hackers, and/or terrorist attacks) – the PPLA urges FDA to tread very carefully when it comes to allowing commercial use of any data that has been submitted to the Agency electronically.

We urge FDA, therefore, to prohibit release of NDA, ANDA, and BLA information that has been submitted electronically, and to use the finalization of this proposed rule as an opportunity to restate the importance of printed PI's in the dispensing of drug products.

On behalf of the entire PPLA, I thank you for the opportunity to submit these comments. Please feel free to contact me at should you have any questions or need additional information.

Sincerely,

Peter G. Mayberry
Executive Director