PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

252 NORTH WASHINGTON STREET, SUITE A • FALLS CHURCH, VIRGINIA 22046
PHONE: 703-538-5799 • FAX: 703-538-6305 • EMAIL: pgmayberry@aol.com

June 9, 2003

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

RE: 21 CFR Parts 201, 606, and 610, Bar Code Label Requirement For Human Drug Products and Blood [Docket No. 02N-0204]

Dear Dockets Manager:

I am writing on behalf of the Pharmaceutical Printed Literature Association (PPLA) with regard to the request for comments on 21 CFR Parts 201, 606, and 610, Bar Code Label Requirement for Human Drug Products and Blood, published as Docket No. 02N-0204 in the March 14, 2003 edition of the *Federal Register*.

While the PPLA commends the United States Food and Drug Administration (FDA) for making patient safety a priority, there are several issues that we would like to call to the Agency's attention with regard to this important rule-making effort. As will be detailed in this comment, we specifically suggest that the following alterations be made before the rule is finalized by the Agency:

- Minor copy changes, including the removal of some copy, should be allowed in order to create space on smaller packages for the safety enhancing bar codes;
- FDA should adopt a streamlined approval process to ensure that any labeling changes needed to meet bar code requirements can be implemented as quickly as possible; and
- The drug product's lot code and expiration date should be required in the bar codes, but only for immediate packaging.

PPLA Background

The PPLA is a not-for-profit trade association chartered in 2001 to serve as the voice of pharmaceutical printed package information manufacturers, and provides a forum for members to promote and improve delivery of information for protection of patients. The PPLA is comprised of member companies that print package inserts, outserts, folding cartons, labels and other components for the pharmaceutical industry, as well as companies that manufacture machinery and raw materials used to produce pharmaceutical printed literature. For more information on our association I invite you to visit our Web site at www.pplaonline.org.

Printed packaging and literature supplied by PPLA members typically contain FDA-approved copy that is intended to help make drugs safe and effective for use by patients. Printed packaging and labeling also supports health care professionals in their duties caring for patients and preventing health problems. PPLA members put enormous effort – and take extreme care – to manage their product and information flows so that the correct label copy accompanies drugs from the time they are manufactured through the time when they are ingested. Bar code technology improves the ability of the entire health care system to manage delivery of the right drug in the right dosage with a much higher degree of accuracy.

02N-0204 C70

PPLA Comments

The PPLA expects that bar codes required by this regulation would be printed on folding cartons as well as on pressure-sensitive and heat seal labels. As such, the PPLA does not anticipate that its members will have any significant problems complying with the proposed requirements. Indeed, we believe the proposed requirements can be implemented by our members within the time frame outlined in the *Federal Register*, and possibly sooner if necessary.

This is primarily due to the fact that bar codes are already printed on many packages and products, and PPLA member companies are currently supporting pharmaceutical manufacturers that have elected to print bar codes on all of their products. Technical specifications for bar codes are also well defined and understood, including a grading process that insures very high reliability in reading when in health care system use.

We note, however, that the amount of space available for printed copy is very limited on the smallest packages, particularly vials and ampoules, and PPLA members have been informed by their customers that – in a few instances – it may be necessary to remove some copy from approved labels to accommodate the bar code. Such copy changes, of course, would require FDA's consent. The PPLA recommends, therefore, that FDA establish a streamlined process for accommodating such requests to facilitate implementation of bar code requirements.

We also note that this regulation could result in changes to large amounts of label copy (using the term to generally describe approved printed information used for inserts, leaflets, and folding cartons and bottle, vial and ampoule labels). While the PPLA believes the time and expense needed to make these changes has the potential to generate tremendous benefits in terms of patient safety, we contend that the proposal would be strengthened if FDA required use of product lot number and expiration date on immediate packaging in addition to the product's National Drug Code (NDC) designation.

With regard to bar code standards, the PPLA suggests that – if FDA chooses a specific standard that would be required for use – the Agency allow enough time for the entire healthcare market to adopt that standard. A primary goal for FDA in this regard should be to prevent the need for duplicating the development of new copy layouts.

Conclusions

The PPLA wishes to be on record in our support of the FDA regulation requiring bar codes on all drug products used in the health care system. If we can provide any information on the technical aspects of printing related applications, please do not hesitate to call upon us.

Sincerely,

Peter G. Mayberry
Executive Director