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The National Professional Society of Pharmacists

June 26, 2000

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

RE: Docket No. 00N-0086

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed amendment of regulations regarding certain label statements on prescription drugs published in the April 10, 2000 Federal Register notice. The American Pharmaceutical Association (APhA), the national professional society of pharmacists, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, and pharmacy students. Pharmacists support measures such as changes to product labeling and package design intended to decrease medication errors and increase patient safety.

The proposed rule is an important step in decreasing medication errors. As a member of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), APhA affirms the Council's 1997 recommendation to the Food and Drug Administration (FDA) to regularly review error-prone aspects of product labeling and package design. Overcrowded prescription drug labels and inconsistency among labels of similar products may contribute to medication errors. APhA appreciates the FDA's attempt to simplify product labeling, however, APhA has concerns about aspects of the rule's implementation relinquished to the manufacturer's discretion.

Prior to dispensing, the label of a prescription drug must bear the symbol "Rx only."
APhA supports the regulation to replace the statement "Caution: Federal law prohibits dispensing without prescription" with the "Rx only" symbol. The "Rx only" symbol should be more easily recognized and will reduce the amount of text on a prescription drug label. However, APhA recommends that the FDA modify the rule in two ways:

1) mandatory placement of the "Rx only" symbol on the main part of the label, and
2) minimum font size for the "Rx only" symbol relative to the other text on the label.

Although the rule requires "prominent and conspicuous" placement on the product label, according to the *Guidance for Industry* published by the FDA, it is merely preferred that the symbol appear on the main panel of the container or label if space permits.[1]

[1] Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 – Elimination of Certain Labeling Requirements. Revised July 1998.

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Conspicuous and consistent placement of the "Rx only" symbol is necessary to insure that prescription pharmaceuticals are not mistakenly identified as over-the-counter products. For example, pharmacy technicians responsible for unpacking wholesaler shipments need a clear, consistent method to identify the status of a product for placement behind the pharmacy counter or on the over-the-counter shelves. Allowing manufacturer interpretation to define prominent and conspicuous placement and the size of the "Rx only" symbol may diminish the rule's intended effect of making prescription drugs more easily identifiable and reducing medication errors. APhA recommends that the FDA require mandatory placement of the "Rx only" symbol on the main part of the label, and establish a minimum font size for the "Rx only" symbol to insure its distinction from other printing on the label.

Repeal the requirement that certain habit forming drugs bear the statement "Warning—May be habit forming."

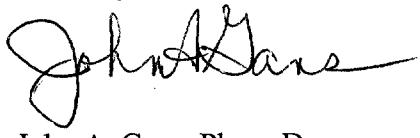
APhA has concern with the repeal of the requirement to include the statement "Warning—May be habit forming" on certain habit forming drugs. The current warning statement serves primarily to remind healthcare providers of the drug's potential to induce physical dependence. In most cases the warning statement serves as a reminder to the pharmacist, with the exception of prescriptions dispensed in their original packaging. It is the responsibility of the pharmacist to inform patients of the potential for dependence. It is unlikely, however, that the warning (as it appears today) provides much information beyond that of which the pharmacist is already aware. As such, removal of the warning is not likely to result in significant problems.

The proposed rule, however, only repeals the requirement mandating use of the warning statement, but does not prohibit its use. This could create confusion in practice, as use of the statement will be <u>optional</u> and not based on product content. Leaving this statement to the manufacturer's discretion could yield some products with a warning, while other similar products may not carry such a warning. Use of the warning statement should not be optional. To avoid confusion, the Agency should choose one of two options: mandate use of the warning or prohibit it from product labeling.

In conclusion, APhA fully supports the intent of the proposed regulation. Measures to improve patient safety are a top priority for our Association and our members—and decreasing confusion from product labeling is an important component of this work. Again, we ask that you consider the potential negative effects of allowing manufacturers wide discretion when implementing the rule. Mandatory placement of the "Rx only" symbol on the main panel of the container or label, and strict guidance on the use or prohibition of the "Warning—May be habit forming" statement will certainly strengthen measures to increase patient safety and increase the effectiveness of this rule.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Group Director of Policy and Advocacy at 202-429-7533, or Susan K. Bishop, APhA's Manager of Regulatory Affairs and Political Action at 202-429-7538 with any questions.

Sincerely,



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