GPhA
Generic Pharmaceutical Association

1620 I Street, NW • Suite 800 • Washington, DC 20006
202-833-9070 • Fax: 202-833-9612 • Email: info@gphaonline.org

June 10, 2003

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

Docket Number: 02N-0204

Proposed Rule: Bar Code Label for Human Drug Products and Blood

Comments of the Generic Pharmaceutical Association

The Generic Pharmaceutical Association commends the efforts of Secretary Thompson and FDA to reduce medication errors and appreciates the opportunity to comment on the proposed rule. GPhA represents 98% of generic drug manufacturers whose drugs are dispensed for almost half of all prescriptions filled in the United States, but account for less than 10% of all drug expenditures. GPhA is the united voice of the generic drug industry and is committed to patient health and safety, and strongly supports any measures that will improve our health care system.

General Comments

In comments made during the FDA public meeting August 2002 and in submitted comments on this issue, GPhA has maintained support for bar coding of human prescription drugs and continues to defer to other stakeholders better able to comment on over-the-counter products and medical devices. Upon review of the proposed rule, GPhA continues to strongly support placing bar codes containing the NDC number on unit-dose labels and certain packaging of all prescription drugs. We agree with FDA that in the absence of supporting data, there should be no requirement to include lot number and expiration date. If data were to exist, or if such information emerges in the future to clearly show that frequency of medication errors would be reduced by inclusion of lot number and date of expiry, GPhA would support inclusion of those into the required bar code, as well. We believe the implementation period of 3 years from date of issuance of the final rule is reasonable except as noted below.

Specific Comments

Type of Bar Code

In reference to section "*II. D. Would the Rule Require a Specific Type of Bar Code? (Proposed § 201.25(c)(1))*", GPhA maintains its previously stated concern that absent careful and deliberate planning regarding standardization of symbologies and data format into which the symbologies will read, a state of uncertainty or confusion might ensue as hospitals, manufacturers, and other stakeholders attempt to predict where and how to make capital investments to assure compatibility between codes and scanners. The proposed rule discusses the pitfalls for FDA of adopting a specific code (other than specifying UCC/EAN compliance) or assembling a committee or body comprised of affected stakeholders to further explore the issue. GPhA is concerned that FDA's stated presumption that "...by the time any final bar code rule becomes effective...bar code scanners will be able to read different UCC/EAN linear bar code symbologies reliably and efficiently" might leave too much to chance. We reiterate our previously stated suggestion that a working group of impacted stakeholders assemble to establish appropriate guidelines for symbology and data format to provide a smoother and more certain path to successful, single-iteration investment to bring this important safety feature to fruition in the most expeditious and least unsure way.

Exemptions

The proposed rule is clear in excluding an exemption provision (*§I. F. What Would Happen if a Bar Code Could Not Be Put on a Product*) because of FDA's concerns that if the provision were abused, and there were a deluge of such requests, the Agency would suffer a substantial resource strain. FDA further states that it believes "...almost all products are capable of bearing a bar code." GPhA believes that FDA should reconsider this stance and provide for limited exemptions to the bar code requirement. FDA's use of the word "almost" in the above cited passage from the proposed rule is an implicit acknowledgement that some products might already exist on which placement of a bar code might be impractical or even impossible. Given the necessity to use novel packaging materials to ensure drug product quality for a relatively small number of products, the regulatory flexibility to provide an exemption or waiver may be critical either now or in the future. It is expected that the number of products that might be eligible for an exemption/waiver would be minimal, but such a provision may be very important to assure compliance with all marketing regulations. Likewise, we ask that FDA consider flexibility in labeling format to accommodate incorporation of bar codes into product labeling. Such flexibility in labeling format may be essential to permit the industry to comply with bar code requirements for products with limited space and/or restricted configurations.

While the existence of UCC/EAN compatible symbologies like RSS provide a means to place a code on even very small vessels, it might not account for all of them, and it might not for all new ones that could arise in the future. Indeed, given the time and resources necessary to implement placement of bar codes on each manufacturing line, and the

uncertainty caused by the proposed rule's incomplete standardization of code, scanner and data format raise the possibility of reassessment of commercial viability of given products. Individual manufacturers are better positioned to speak about potential impact on cost effectiveness for particular products, but GPhA understands that technological challenges could preclude the availability in the market place of certain drugs, specifically certain dosage forms. Given this potential to impact dosage form availability for a limited number of drugs, GPhA recommends that FDA include an exemption provision in any final rule.

The Generic Pharmaceutical Association appreciates this opportunity to comment on this important proposed rule, the outcome of which would be increased patient safety through medication error reduction. We continue to support FDA efforts to devise an appropriate, well-planned system to effect this change and again offer our assistance as mentioned above and in previous comments on this issue.

Please do not hesitate to contact us for further discussion.

Sincerely,

Kathleen D. Jaeger
President &CEO