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July 28, 2005

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

Ref: Final Rule on **Bar Code Label Requirement for Human Drug Products and Biological Products**, *Federal Register*, February 26, 2004; and Draft Guidance on **Bar Code Label Requirements- Questions and Answers**, *Federal Register*, June 7, 2005.

Pfizer would like to acknowledge the effort put forward by the FDA in the preparation of the subject final rule and draft guidance. Pfizer is in support of the use of bar codes in labels. Pfizer believes, as does the FDA, that many dispensing errors can be avoided with the use of barcodes to properly identify the product at the unit of use or unit dose level. These barcodes would be scanned at the point of dispensing along with a patient's wristband to ensure the right dose of the right product is given to the right patient at the right time. The effective date of the final rule is April 26, 2004.

Section II.I of the final rule (*I. How Will We Implement the Rule?*) indicates "...for drugs that are approved on or after the effective date of this rule, we would expect compliance within 60 days after the drug's approval date...for drugs approved before the effective date of this rule, we would expect compliance within 2 years after that date...A 2-year implementation period will also enable firms to exhaust existing stock. If a drug has an expiration date that exceeds 2 years, and the drug was not subject to the bar code requirement at the time it was marketed, we will allow that drug to remain on the market without a bar code. However, we recognize that we cannot preclude the possibility that some drug products may be difficult to bar code, either because of their containers, size, or other complications. Therefore, if a manufacturer, repacker, relabeler, or private label distributor can demonstrate to us that, for technological reasons, it cannot comply within 2 years after the final rule's effective date, it should contact us..."

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Response to Q7 in the draft guidance (*How is the 2-year implementation date intended to work?*) reads "A7: The 2-year implementation date is for drug products that received approval before April 26, 2004. This 2-year period is intended to provide the industry sufficient time to make the labeling changes necessary to comply with the rule by April 26, 2006. Drugs approved on or after April 26, 2004, have 60 days from their approval date to comply with the bar code rule."

Pfizer has a concern that this section of the regulation can be interpreted as all product shipped after April 26, 2006, must comply with the regulation. This interpretation will make compliance to the rule hard to enforce both for industry and the FDA and may necessitate relabeling or repackaging goods which have already been packaged but not yet distributed, increasing the potential for disruption of product supply. Pfizer believes that the benefits of this interpretation (product shipped after April 26, 2006, must comply with the rule), which will be a lower risk of incorrect dispensing, do not outweigh the burden of conducting the repackaging and relabeling operations. Further, Pfizer believes that the FDA did not intend to create such a burden when they developed the implementation date of two years from implementation of the rule (vs. the three years which was originally proposed.) Therefore Pfizer respectfully requests that the agency publish an official restatement of the terms of compliance, stating that all products PACKAGED on or after 4/26/06 must contain bar codes.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Migliaccio", with a long horizontal flourish extending to the right.

Gerald P. Migliaccio
Vice-President
Global Quality and EHS Operations