Wyeth Pharmaceuticals

Wyeth

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June 12, 2003

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

RE: Comment on Docket No. 02N-0204
Proposed Rule – Bar Code Label Requirement
For Human Drug Products and Blood

Dear Sirs:

Wyeth Pharmaceuticals (Wyeth), hereby submits comments to Docket No. 02N-0204, pertaining to the proposed rule on **Bar Code Label Requirement For Human Drug Products and Blood** published in the *Federal Register*, Volume 68, Number 50, pages 12500-12534 (March 14, 2003).

Wyeth is one of the world's largest research-based pharmaceutical and healthcare products companies, and is a leading developer, manufacturer and marketer of prescription drugs, vaccines and over-the-counter medications. Wyeth acknowledges the Agency's efforts in this proposed rule to require certain human drug product labels and biological product labels to have bar codes. We support the goal of reducing hospital-dispensing errors and enhancing patient safety.

We respectfully submit the following comments on the proposed rule.

Who Would Be Subject To the Barcode (Proposed §201.25(a))

The proposed regulation would require companies that repackage pharmaceutical products to barcode their packaging. It also permits the use of UCC/EAN 128 or RSS limited or stacked as the barcode. All of these barcodes have a packaging indicator built into the code structure to differentiate various levels of packaging (ie, the code will differentiate an individual blister from a carton containing 100 blisters). The proposed regulation, however, does not address how drug repackagers will uniquely identify their package from the original manufacturer's package. To help address this, Wyeth recommends the following alternatives be considered:

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1. Drug manufacturers use 0,1,2,3 or 4 as packaging indicators and repackagers use 5,6,7 and 8
2. Drug repackagers be required to have a Manufacturer ID assigned by the FDA

Lot Number and Expiration Date

The main objective of the proposed rule is to reduce medication errors. Bar coding the NDC number as identified in the regulation accomplishes this goal. The inclusion of the lot number and expiration date would make it easier to identify recalled or expired drugs. Data the Agency has tabulated from the adverse event reporting system and the Office of Compliance, however, has not been sufficient to determine any elevated public health problem resulting from administering recalled or expired drug products. Adding the lot number and expiration date may require manufacturers to acquire additional equipment significantly adding to the cost of bar coding. Since no added benefit has been demonstrated, Wyeth supports FDA's position that the lot number and expiration date not be required in the bar code at this time, but it should remain an option of the manufacturer.

Bar Code Standard and Data Elements

The regulation as it is currently written in proposed §201.25(c)(1) prohibits the use of two-dimensional barcodes and only permits linear codes. As a vaccine manufacturer, Wyeth would recommend that DataMatrix be permitted on an exception basis on small vaccine labels or packages, or on OTC packages with Drug Facts information where RSS would be difficult or impossible to fit on a label or pouch at an 8.3 or 10 mil density. DataMatrix can encode the same information as RSS in 1/3 of the space.

The issue of limited space on small vials, ampules and blisters has not been addressed in this regulation. The Uniform Code Council (UCC) is recommending that human readable information appear either above or below the barcode. Many Wyeth small packages do not have sufficient space to print both the human readable information and the barcode. Wyeth recommends that the regulation clearly specify which text may be removed from small package labels and under what circumstances in order to provide space for the addition of a barcode.

Products Requiring a Bar Code (§201.25(b))

The proposed regulation, as it is currently written, would require manufacturers to barcode all prescription drugs down to the unit dose. Packaged diluent would also be required to have a bar code. Wyeth proposes eliminating the requirement for

barcodes on diluents co-packaged with product, since there could be potential for mis-identification after the diluent has been reconstituted with the product.

The proposed regulation does not address the issue of pharmaceuticals packaged in low-density polyethylene form fill and seal containers. These containers currently have no printing on them due to issues with potential extractables. If the intent of the proposed rule is to include bar codes on such packaging, Wyeth recommends additional implementation time in order to conduct appropriate stability testing and obtain prior approval by the Agency.

Over-The-Counter Products

The proposed regulation does not adequately define the OTC drugs that must be bar coded. OTC drugs are often sold to distributors and in turn may be resold to hospitals without the knowledge of the manufacturer. Lacking an adequate definition of what is meant by "commonly used in hospitals," drug manufacturers run the risk of having their product recalled as being mislabeled for not having a barcode on the package.

Certain OTC drug products are required to bear a UPC, UCC/EAN 128 or RSS linear or stacked barcode. That barcode is required to encode the manufacturer's NDC number and, therefore, would be able to satisfy the proposed rule. Most OTC drug products bear an UPC symbol but that symbol does not necessarily contain the manufacturer's NDC number. In addition, many companies have more than one UPC for a given SKU and as the regulation is currently written, most OTC product labels would need to add a second barcode for the NDC number or revise their current practice. Inasmuch as UPC barcodes correctly identify the product, the use of UPC barcodes on OTC drug products should be permitted in the final regulation.

Proposed Implementation

If a final rule were issued as written, bar codes would be required on human prescription drugs and OTC drugs dispensed under an order and commonly used in hospitals within three years after publication in the *Federal Register*. The Agency notes that this implementation schedule would permit sufficient time to obtain NDC numbers, exhaust supplies of existing labels, and have new labels made that contain the bar code or machine-readable information. Wyeth supports this implementation schedule, with the exception for low-density polyethylene form fill and seal containers for the reasons noted above.

Wyeth

This letter is submitted in duplicate. Wyeth appreciates the opportunity to provide this constructive input to the rulemaking process. Please contact the undersigned at 484-865-3794 if there are any questions regarding the submitted comments.

Sincerely,

Roy D. Baranello, Jr.
Assistant Vice-President
Worldwide Regulatory Affairs