PDA
An International Association For Pharmaceutical Science And Technology
Suite 1500
3 Bethesda Metro Center
Bethesda, MD 20814 USA
Tel: (301) 986-0293
Fax: (301) 986-0296
www.pda.org

June 13, 2003

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

2967 '03 JUN 13 P1:00

RE: [Docket No. 02N-0204]

Dear Sir or Madam:

The PDA is pleased to provide these comments on the Proposed Bar-Code Rule. PDA is an international professional association of more than 10,500 individual member scientists having an interest in the fields of pharmaceutical manufacturing and quality. The Proposed Bar-Code Rule will affect a substantial number of our members. Our comments were prepared by a group of international experts in this field.

1. The Proposed Rule does not contain exclusions for certain types of products or packaging. A nebule (used to fill a nebulizer) is identified via impressions on its plastic container and does not have paper label on which to imprint a bar code.

In the Early 1990's CDER issued the following statement:

"LDPE Containers

The Center for Drug Evaluation and Research at FDA wishes to apprise you of a concern regarding inhalation products used to treat asthma and/or chronic obstructive pulmonary disease. This concern involves LDPE containers used for inhalation products because they might allow entry or exit of substances from the drug product and thus affect its identity, strength, quality and purity. Examples include:

- Water loss through an LDPE container that alters the concentration and tonicity of the drug product;
- Permeation of oxygen or carbon dioxide across LDPE that might affect the stability of the product:
- Entry of volatile organic molecules into the drug product from sources such as the manufacturing process, packaging components, or adhesives and inks applied to the container.

Accordingly, the Center requests that all manufacturers of inhalation products intended for the treatment of asthma that are packaged in LDPE

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containers use a secondary overwrap, such as a laminated foil, or demonstrate to the FDA that such an overwrap is unnecessary to insure and maintain the identity, strength, quality and purity of the drug product. Center review staff are available to assist manufacturers in meeting this objective."

Part of this effort was to remove labels from the nebules and identify the product through embossing. To date, CDER, and OGD have been reluctant to approve nebule products with a label. Without allowing a firm to place a label on the nebule, it is unclear how the firm is to print the bar code. This question was asked at the open meeting, but no answer was provided at the time. Please note that placing any paper inside an outer pouch compromises the product, even if it is on the lower tip of the nebule.

2. On small items such as "blister packs," or one or two mL small volume parenteral syringes, the only way to add room for a bar code would be to reduce the font size of the printing to a point that it would be difficult to read.

The FDA has concern about the readability of the blister lidstock printing. FDA has in the past allowed for reduced information on the labeling of the individual units and specialized a font size for the information that remains. Adding the barcode to each individual unit, will necessitate additional changes in order to incorporate the barcode.

At the present time the following information is listed on each unit:

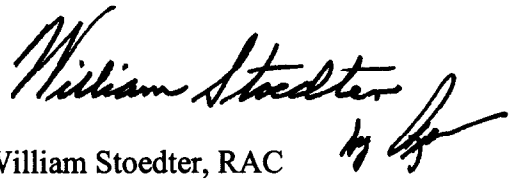
- Name of the drug,
- Strength of drug
- Manufacturers name
- Lot number
- Expiration date, and
- CRC may contain instructions to open the container.

3. It is not clear if diluents would be subject to this rule, they are not drugs but some do have NDC numbers and for some drugs the diluent used is critical and specified.

The proposed rule did not provide any direction on whether a diluent vial supplied along with the drug should be bar coded or not. Some lyophilized medications are supplied with water for injection or other diluent for reconstitution of the powdered drug product prior to intravenous or intramuscular administration. Currently this diluent supplied with the active ingredient is not required to include a NDC number. The diluent is not an active drug and consequently cannot have a NDC number. Therefore, the PDA Task Force strongly feel that diluent vials should be excluded from the bar code requirement.

If you have any questions regarding our comments, or how we may assist with further development of the draft, please contact me.

Sincerely,



William Stoedter, RAC
PDA Director of Regulatory Affairs
stoedter@pda.org