ALPHARMA.
U.S. Pharmaceuticals Division

June 11, 2003

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

Re: Bar Code Label Requirement for Human Drug Products and Blood (Proposed Rule published March 17, 2003)

Ladies and Gentlemen:

Reference is made to the proposed rule entitled Bar Code Label Requirement for Human Drug Products and Blood, published in the Federal Register on March 17, 2003 and the agency's guidances [1,2] applicable to semipermeable container closure systems.

Alpharma has reviewed the Bar Code proposed rule and is commenting on the difficulties in placing a scannable bar code on inhalation drug products packed in semipermeable container closure systems. Alpharma currently markets three drug products that are packaged in embossed semipermeable vials, Albuterol Sulfate Inhalation Solution, Cromolyn Sodium Inhalation Solution, and Ipratropium Bromide Inhalation Solution. The vials, for these products, are packaged in foil overwraps, which are then cartoned for distribution.

The proposed rule requires a bar code to be placed on the drug's label. It is not possible, using current technologies, to incorporate a bar code using an embossing technique on a semipermeable vial. Furthermore, in accordance with the applicable published guidances [1,2], it is recommended that semipermeable containers are embossed or debossed, and not labeled. It is preferable not to place a label on the vial, in order to include a scannable code, as this introduces the potential for contaminants leaching from the label into the drug product, compromising the integrity of the product. Therefore, for semipermeable

[1] Guidance for Industry: Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation (July 2002)
[2] Guidance for Industry: Inhalation Drug Products Packaged in Semipermeable Container Closure Systems (July 2002)

Alpharma USPD, Inc. 200 Elmora Avenue Elizabeth, NJ 07207 Tel (908) 527-9100 Fax (908) 659-2440

container systems, rather than require the bar code to appear on the immediate container label, it would be preferable to revise the requirement to allow for the scannable barcode to print on the foil overwrap. This would still allow for the barcode to be scanned at the time of dispensing, as the vials must be stored in the foil overwrap, while eliminating the possibility of contaminating the drug product with leachables from a label.

Alpharma appreciates the opportunity to present our comments and hopes you will take them into consideration while preparing the final rule.

Should you have any questions or require further clarification, please do not hesitate to contact us.

Sincerely,

ALPHARMA USPD INC.

Joan Janulis, R.A.C.
Vice President, Regulatory Affairs