MEMORANDUM OF MEETING

between the Food and Drug Administration and
the Pharmaceutical Research and Manufacturers Association

August 19, 2002
1615 L Street, NW
Suite 1260
Washington, DC

Attendees:

PhRMA
Alan Goldhammer, PhRMA and members of the PhRMA Bar Code Task Group

FDA
Thomas McGinnis, Office of Policy, Planning, and Legislation
Erica Keys, Office of the Chief Counsel
Jerry Phillips, Center for Drug Evaluation and Research
Mary Gross, Center for Drug Evaluation and Research

The focus of the meeting was to give FDA participants the industry perspective on bar codes, the current use of the NDC number within the EAN/UCC system, current use of bar codes by pharmaceutical firms, types of bar codes available, and diffuculities encountered by member firms in the bar coding operations. Industry representatives suggested that the main reason bar codes have not appeared on many unit dose tablets and capsules to date was that there has not been much demand for it. If the demand existed the indusrty might be able to add not only NDC number in bar code format, but also the lot number and expiration date.

FDA explained that its goal and that of Secretary Thompson was to increase patient safety and that one way to accomplish this was through the use of barcodes.

PhRMA ecouraged FDA to consider both current technologies when developing a proposed rule and to maintain flexibility for the industry. The use of bar codes is one method of inventory control besides patient safety.

PhRMA presented samples from Pfizer showing the difference between two possiblc bar coding approaches. There was a presentation of possible small package configurations; some aspects of the presentation assumed possible regulatory relief from current FDA labeling requirements to provide adequate room for the bar code, drug name, and dosage strength. However, PhRMA indicated that it did not believe that the data supported inclusion of lot number and expiration date information in a bar code at the point of administration, although the information might be helpful at pharmacies.

PhRMA stated that its goal is to increase patient safety and alleviate the otherwise-avoidable mistakes that are occurring through the flexible application of innovative technology.