



Food and Drug Administration
Rockville MD 20857

• AUG 25 1997

Eugene S. Peiser, Ph.D.
Eugene S. Peiser & Associates
439A Causeway Blvd.
Dunedin, FL 34698

Dear Mr. Peiser:

The use of the National Drug Code/labeler code, on prescription drug products, by chain drug stores and wholesale repackers was discussed with you during a March 6, 1997 meeting. At that time, you informed the agency that in 1996 some of the repackers you represent began to have their drug listing forms returned because their labels contained the manufacturers NDC/labeler code. You stated you did not believe the agency had given proper consideration to the problem this has created.

As discussed, the National Drug Code number (NDC), which consists of a labeler code assigned by the agency, is requested but not required to appear on all drug product labels. When the NDC is included in the product labeling, its use should conform to the format prescribed in 21 CFR 207.35 (b)(3).

The agency is aware that it is the practice of the trade to include the NDC on product labeling. We also recognize that most companies use the labeler code assigned to them by the agency and other companies do not.

We agree that the use of manufacturers NDC/labeler code by repackers should be thoroughly examined and we are currently reviewing the issue. There will be an opportunity for public comment in this arena at the appropriate time.

In the interim, we will not return repackers drug listing forms that use the manufacturers NDC/labeler code on the product label.

Sincerely yours,

A handwritten signature in cursive script that reads "Kathy P. Miracco".

Kathy P. Miracco
Deputy Director
Division of Prescription Drug
Compliance and Surveillance
Office of Compliance
Center for Drug Evaluation and Research

cc: The National Association of Chain Drug Stores, Inc./J. Coster