Nelco

LABORATORIES, INC.

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Division of Dockets Management (HFA-305)
Food And Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. 2005N-0430 and RIN 0910-AA49

Dear Sir or Madam:

This correspondence is in response to the Proposed Rule in the Federal Register dated August 29, 2006 dealing with Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, including Drugs that are Regulated under a Biological License Application, and Animal drugs.

As a Licensed Manufacturer of Biological Parenteral drugs, Nelco Laboratories, Inc. produces over 300 Bulk Allergenic extracts and approximately 2,000 prescription orders per year, which can contain anywhere from one (1) to twelve (12) Bulk products in a mixture. These prescription vials can be a-one (1) vial maintenance or a four (4) to five (5) vial treatment set.

The labels for these products are too small to incorporate all of the allergens that make up these mixtures so we have to list them separately on their individual box labels.

We feel that including NDC codes as the Proposed Rule states will be a great burden to the Allergenic Manufacturers and would cause some confusion and errors as to the initiatives stated by the FDA

Thank You for your attention to this matter

April Catanzaro

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