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A PETITION

To: The Commissioner of  
The United States Food and Drug Administration

Submitted by Eugene S. Peiser, Doctor of Pharmacy, President, Peiser & Associates Inc.  
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### **Purpose of Petition**

**To compel the Agency to follow the requirements of the Drug Listing Act of 1972.**

**(The Act requires the listing of ALL human and veterinary drug products, FDA does not adhere to the requirements of the Act and should be compelled to do so to reestablish public confidence in its actions to protect the public health)**

**Adequate time has elapsed since the passage of the Act for the Agency to have complied.**

## Basis of Petition

In 1972 the Federal Food, Drug and Cosmetic Act was amended to make the submission of information on all commercially distributed drugs MANDATORY. The Drug Listing Act dictated the expansion of the NDC System to include human over the counter drugs and veterinary drugs, in addition to prescription drugs.

The impact of the Drug Listing Act made it necessary to suspend publication of the NDC Directory until its provisions could be implemented and all submitted data could be processed.

In complete DISREGARD of the intent of the legislation, the FDA has not complied with the provisions expressed in the law.

Between 1973 and 1976 only one National Drug Code Directory was published, that being in 1976. It was limited to human prescription drugs, and selected over the counter drugs including insulin and other OTC products which physicians often prescribe.

In 1980 a NDC Directory was published followed by the 1982 and 1985 directory.

The 1995 edition of the NDC Directory also did not comply with the provisions of the law as directed by Congress.

The present NDC Directory as listed as of 8/1/06 (FDA Website) does not comply with the law. The current Directory that appears on the FDA Web does not list ALL Human and Veterinary Drugs as required by the Law.

FDA requires that all registered firms MUST submit a current list of all drugs manufactured, prepared, propagated, compounded or processed.

The FDA does not place this information into its data base (NDC Directory)

Environmental Impact of this petition

**NONE**

**ZERO**

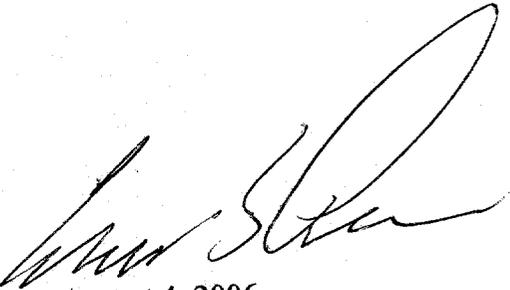
The inordinate amount of time & money spent by the many firms that are presently filling out FDA form 2657 for each individual drug product is a waste of resources, since the FDA does not follow the intent of the law. ( Not placing this information in the NDC Drug Directory where it can be retrieved and used when necessary)

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petition which are unfavorable to the petition.

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