DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 21 2012

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harold L. Peiser
Peiser & Associates, Inc.
P.O. Box 774
Palm Harbor, FL 34682

Re: Docket No. FDA-2006-P-0343

Dear Mr. Peiser:

According to the records of the Food and Drug Administration's Division of Dockets Management, the petition referenced above[1] has not been resolved.

As part of the Agency's efforts to reduce the backlog of unresolved citizen petitions, the Center for Drug Evaluation and Research (CDER) has reviewed the unresolved petitions assigned to it for action. One goal of this review is to identify citizen petitions submitted more than 5 years ago that petitioners may believe are no longer timely. CDER believes that having to respond to these old petitions diminishes the Center's capacity to address in a timely fashion pressing public health issues. Therefore, these petitions have a lower priority, and it is unlikely that the Center will have the resources to respond to them soon.

The referenced petition was submitted more than 5 years ago by Dr. Eugene S. Peiser, President of Peiser & Associates, Inc. A review of the docket shows that the petition has been inactive for many years. Furthermore, at this time, we have become aware that Dr. Peiser has passed away. In addition, given the length of time since the petition was submitted and developments related to the National Drug Code Directory, we are uncertain as to whether the views expressed in the petition reflect the current views of Peiser & Associates, Inc.

Accordingly, we have enclosed a copy of the petition and would appreciate it if you would review it and respond to the docket number listed above if you wish to keep this petition active. Your response should reference the docket number and may be sent to the Food and Drug Administration, Dockets Management Branch, Room 1061, 5630 Fishers Lane, Rockville, MD 20852; or submitted electronically at www.regulations.gov. If we do not receive a written response from you within 30 days from the date of this letter, a copy of this letter will be filed in Docket No. FDA-2006-P-0343 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

[1] This citizen petition was originally assigned docket number 2006P-0310. The number changed to FDA-2006-P-0343 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

FDA-2006-P-0343

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Docket No. FDA-2006-P-0343

If you have any questions, please contact Kristiana Brugger of my staff at 301-796-2897. Thank you for your attention to this matter.

Sincerely,

Nancy K. Hayes
Director, Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

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.
FDA Compliance Consultants

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2006P-0310

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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.

Eugene S. Peiser
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President, Peiser & Associates, Inc.
FDA Compliance Consultants

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August 4, 2006