Peiser & Associates, Inc.
FDA Compliance Consultants
PO Box 774
Palm Harbor, Florida 34682
727-789-2954 Fax 727-785-9941
http://peiserconsulting.com
HLPeiser@tampabay.rr.com

May 29, 2012

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

Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers Lane
Rockville, MD. 20852

Dear Ms. Hayes,

The views of Peiser & Associates, Inc. re: Docket No. FDA-2006-P-0343 is the same as the day the Petition was presented to the FDA. Peiser & Associates, Inc. wishes to keep this Petition active and address it ASAP as the FDA as a Federal Agency is expected to obey Federal Law.

Harold Peiser
President
Peiser & Associates, Inc.
FDA Compliance Consultants
PO Box 774
Palm Harbor, Florida 34683

DEPARTMENT OF HEAL[illegible] & 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.

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

Peiser & Associates, Inc.
FDA Compliance Consultants
P.O. Box 774
Palm Harbor, FL. 34682

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT
OF THE RETURN ADDRESS, FOLD AT DOTTED LINE

CERTIFIED MAIL™

7011 2970 0002 9483 2652

UNITED STATES POSTAL SERVICE

1000

20852

U.S. POSTAGE
PAID
OZONA, FL
34660
MAY 31, 12
AMOUNT

$5.75
00069976-01

JUN 07 2012

Mail Screening Facility

Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers Lane
Rockville, MD. 20852

2065780001 C000