DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661	12/12/2006 - 12/18/2006
	FEI NUMBER 2411192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Robert P. Reichman, Vice President Worldwide Quality Assurance

FIRM NAME	STREET ADDRESS
Nice Pak Products, Inc.	2 Nice Pak Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orangeburg, NY 10962-1317	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, the firm did not complete a change control form for the planned deviation in the manufacturing process for NDA (B)(4) The current process for commercial batches does not undergo a filtration step that was submitted in the application and approved in June 2005.

Since the approval, there have been approximately (b)(4) batches of (b)(4) manufactured.

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Simone E. Pitts, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
12/18/2006