



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1870d

WARNING LETTER

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

OCT 1 2 2001

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WL-I-11/01

Trang, "Tracy" Nguyen, Marketing Director/Owner  
NDT Pharm Management, LLC  
13071 Brookhurst St., # 150  
Garden Grove, CA 92843

Dear Ms. Tracy Nguyen:

On 8/21-28/2001, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 13071 Brookhurst St. # 150

The inspection was conducted to determine the firm's compliance with FDA's Import for Export laws, in accordance with section 801(d)(3) of the Federal Food, Drug and Cosmetic Act (the Act) or section 351 (h) of the Public Health Service Act (PHSA).

The FDA Export Reform and Enhancement Act of 1996 ("Export Reform Act", Public Law 104-134) became law on April 26, 1996. Under this new provision of the Act (section 801 (d)(3), importers wishing to import violative products that are intended for manufacturing or processing and are subsequently exported must provide FDA with notification, at the time of initial importation, that the drugs are intended to be incorporated or "further processed" by the initial owner or consignee, into a product that will be exported.

The initial owner or consignees of the article: must maintain records of the use of such imports; must maintain control of the imported product and must have documentation of the destruction or exportation of any article or portion not used in the exportation or destruction of the product.

Our inspection revealed that during the time period of 1/14/2000 through 3/28/2001 you imported for export a total of [REDACTED] entries covering approximately [REDACTED] various prescription drugs for export.

Our investigation further revealed that out of the [REDACTED] drug entries, no records were maintained on the exportation of these drugs.

These articles are also drugs within the meaning of Section 201(g) which may not be introduced or delivered for introduction or delivered for introduction into interstate commerce under Section 505(a), since they are new drugs within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for such drugs.

The above identified violations are not intended to be all inclusive of the violations noted at your facility. It is your responsibility, as importer of record, to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office, in writing, with 15 working days of receipt of this letter and of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state reason for the delay and the time within which the correction will be completed.

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Your written reply relating to these concerns should be addressed to:

Irene Gomez, Director  
Import Operations Branch  
Los Angeles District  
U.S. Food and Drug Administration  
222 West 6<sup>th</sup> Street, Suite 700  
San Pedro, CA 90731

Sincerely,

  
Alonza E. Cruse, Director  
Los Angeles District  
U. S. Food and Drug Administration