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# U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT  
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

Telephone: [718] 340-7000 [Ext 5301]

## **WARNING LETTER**

### **CERTIFIED MAIL** **RETURN RECEIPT REQUESTED**

Mr. Joseph J. Mollica  
President  
LNK International, Inc.  
60 Arkay Drive  
Hauppauge, New York 11788

May 27, 1997

REF: 54-NYK-97

Dear Mr. Mollica:

During an inspection of your drug manufacturing facility located in Hauppauge, New York, conducted between the dates of April 14 and May 14, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug products, Enteric Coated Aspirin Tablets, 325 mg and 500 mg, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products:

- a) There is no validation data for the manufacturing process for Enteric Coated Aspirin Tablets, 500 mg.
- b) A specified range or limit to the quantities of coating solution components used to process Enteric Coated Aspirin Tablets, 325 mg and 500 mg has not been established by validation and verified to be consistent with the specified target tablet weight gain.
- c) Samples collected and tested for validating the compression process for the Enteric Coated Aspirin Tablets, 325 mg were not representative of the entire compression process.
- d) Validation batches of Enteric Coated Aspirin Tablets, 325 mg, P13932 and P13933, were processed using a coating spray rate, spray pressure and spray temperatures which differed from the current master formula instructions.

2. Master production and control records fail to include complete and accurate manufacturing instructions for Enteric Coated Aspirin Tablets, 325 mg and 500 mg:

- a) Manufacturing instructions fail to include a limit or range for the quantity of coating

solution to be used in the manufacture of batches. Manufacturing instructions include the statement that additional quantity may be used. For example, batches P16842, P16827 and P16793 of Enteric Coated Aspirin, 500 mg were each processed with a different quantity of coating components then specified in the master record.

b) Manufacturing instructions fail to include complete spraying instructions for tablet coating. For example, the number and distances of spray guns are not specified.

**3. Failure to follow batch production and process control procedures:**

a) Batches, P16601, P16583, P16628 of Enteric Coated Aspirin Tablets, 325 mg were manufactured with a different quantity of precoat then specified on the master formula instructions.

b) Although the master formula instructions specify that coat spraying is to achieve 7-8% weight gain, batches, such as, P15587, P15588, P16842, P16827, P16793 of Enteric Coated Aspirin Tablets, 500 mg, were manufactured by spraying a coating until a weight gain of up to 9% was achieved.

**4. Batch production records for Enteric Coated Aspirin Tablets fail to record the quantities of coating solution actually used/sprayed into each coating pan.**

**5. Failure to have a written record of investigation into discrepancies or the failure of a batch or any of its components to meet specifications, as follows: Enteric Coated Aspirin Tablets, 500mg batches; P15587, P15588, P16842, P16827, P16793, failure to meet tablet weight specifications.**

**6. Failure to follow established complaint handling procedures. Complaints involving the dissolution failure of batches of Enteric Coated Aspirin Tablets were not entered onto the records, logs, and reporting system as required in the written standard operating procedure.**

**7. Failure to conduct stability testing of each formulation of Enteric Coated Aspirin Tablets. For example, batches, P16601, P16583, P16628 of Enteric Coated Aspirin Tablets, 325 mg were manufactured with a precoat formula which differs from the formulation specified in the master record.**

The above identification of violations and the observations on the FDA 483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. As a manufacturer of drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action

cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

We have received your letter dated May 23, 1997 stating that your firm is taking prompt action to correct deficiencies, and that a detailed response to the FDA-483 is being prepared. Your response should address the specific violations noted in this letter as well as the Inspectional Observations issued on the FDA 483 at the end of the inspection.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 850 Third Avenue, Brooklyn, NY 11232, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,



Lillian C. Aveta  
Acting District Director

cc: NE1 through NE100  
cc: NE100  
cc: NE140 (QA) -  
cc: NE150  
cc: NE1500  
cc: HFI-35  
cc: HFA-224  
cc: HFC-210(CFN-2432212)via banyan -  
cc: HFD-300  
cc: warning letter file (54-NYK-97) -  
cc: EF(LNK Int'l)  
cc: circ./chrono  
cc: LDD(3) -