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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-72

June 24, 1999

Mr. David Popofsky, Chairman of the Board
Naturopathic Labs International, Inc.
60 Madison Avenue
New York, NY 10010

Dear Mr. Popofsky:

During an inspection of your facility located in St. Petersburg, Florida on February 2-11, 1999, FDA Investigator Shari J. Hromyak determined that you manufacture Nature's Chemist topical ointment, which is labeled for conditions which cause it to be considered a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that the drug you manufacture is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for its manufacturing, processing, packing, or holding do not conform or are not operated or administered in conformity with the Good Manufacturing Practice (GMP) Regulations to assure that your drug meets the requirements of the Act as specified in Title 21, Code of Federal Regulations, Part 211, as follows:

1. Failure to validate the manufacturing processes for Nature's Chemist; or perform any in-process testing to demonstrate that the process maintains a homogeneous mixture throughout filling; or that the potency of the active ingredient is consistent throughout the batch.
2. Failure to maintain proper record keeping practices, in that records are not completed concurrently with the action covered by the record. For example, batch records were completed retrospectively and only after the missing entries were brought to management's attention by the FDA Investigator.

Mr. David Popofsky
Page 2
June 24, 1999

3. Failure to have written specifications for components and container-closure systems including specific identity tests for each component, and specifications for retesting or re-examining components after storage for long periods; and failure to receive and maintain certificates of analysis (COA's) for each lot of drug component received.
4. Failure to establish specifications for finished product acceptance, including sampling, analytical specifications, and test procedures; or verify or audit the finished product analysis performed by the contract testing laboratory.
5. Failure to conduct a stability testing program using the current marketed container/closure system that will support a four (4) year expiration date or an expiration date exemption and to establish a written stability test program that includes visual examination of samples for deterioration of product.
6. Both Master and Batch production records are inadequate and incomplete in that they fail to contain information required by regulations, including: product strength; theoretical yield; product container/closure description; actual vs theoretical yield; remanufacturing procedure records; labeling; fill weight checks; and, finished product inspection results. Batch records are also not completed, in that information asked for is not recorded.
7. Failure to validate cleaning procedures of mixing, storage, and filling equipment; no written cleaning schedule has been established; nor is equipment cleaned after each batch.
8. Failure to establish and maintain procedures covering labeling control operations that include receipt, sampling, issuance, and reconciliation.
9. Failure of the quality control unit to update all procedures and specifications to reflect current operations for the product now in production, Nature's Chemist; and, failure to review all product records annually to determine the need for such changes.

Mr. David Popofsky
Page 3
June 24, 1999

10. Failure to maintain reserve samples of all lots of finished product in each container/closure marketed; failure to maintain reserve samples of any active ingredients; and, failure to document any inspection of reserve samples.

We have received letters from your attorney dated February 23, 1999, and March 12, 1999, promising correction and a further response by April 1, 1999, to provide the status of your corrective efforts. We have not received anything subsequent to the March 12th letter advising what corrections have been completed or providing examples of new forms/procedures.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Please refer to the List of Inspectional Observations (Form FDA 483), which was left with Jan D. Knigge, Senior Vice President, by the investigator at the close of the inspection (copy enclosed).

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

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

Your response should be sent to the Food and Drug Administration, Orlando District Office, 555 Winderley Place, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,



Douglas D. Tolen
Director, Florida District

Mr. David Popofsky
Page 4
June 24, 1999

cc: Scott Popofsky
President

Jan D. Knigge
Senior Vice President
Naturopathic Labs, Int'l, Inc.
12061-B 31st Court North
St. Petersburg, FL 33716