



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

HF1-35  
M 1954N

NEW YORK DISTRICT  
850 THIRD AVENUE  
BROOKLYN, NY 11232  
TEL. (718) 340-7000

**WARNING LETTER**

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

July 30, 1998

Robert A. Barathy, President  
Phoenix Cosmetics Laboratories, Inc.  
925-14 Lincoln Avenue  
Holbrook, NY 11741

Ref: 37-NYK-98

Dear Mr. Barathy:

During our June 13 through June 29, 1998 inspection of your facility located at 925-14 Lincoln Avenue, Holbrook, New York, we determined that your company manufactures over the counter drug products, such as, mouthwash, labeled to destroy organisms related to plaque, psoriasis cream, acne cream, hemorrhoid cream. Our investigator documented deviations from Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the drug products manufactured by your firm, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

At the conclusion of the inspection, the investigator presented to you a list of Inspectional Observations (Form FDA-483) and discussed the findings. The following deviations pertaining to the manufacture of drug products were found:

**PRODUCTION AND PROCESS CONTROLS:**

- a) Failure to have and implement written procedures for production and process controls designed to assure that drug products have the identity, strength, quality and purity they purport or are represented to possess.
- b) Failure to have written procedures in place to assure that any deviations from the established production and process controls are justified and documented.

**MASTER PRODUCTION AND CONTROL RECORDS:**

- a) Failure to establish and follow a system for preparation and approval of master production and control records for drug products.

- b) Failure to ensure that master production and control records contain complete information relating to the manufacture and control of each drug product. Master production and control records lack the following:
- the signature of the individuals who prepared and independently checked the document.
  - statement of the theoretical yield, including maximum and minimum percentages of theoretical yield beyond which investigation is required.
  - complete manufacturing instructions, sampling and testing procedures.
- c) Failure to maintain approved master production and control records for each batch size of drug product manufactured.

#### BATCH PRODUCTION AND CONTROL RECORDS:

- a) Failure to maintain batch production records for all batches of drug products produced. Examples are: batches of Acne cream batch #A97; Hemorrhoid cream Batch#F47; Psoriasis cream Batch #A97; Calendula cream batch# G47.
- b) Failure to ensure that batch production records contain complete information relating to the manufacture and control of each drug product. Batch production records lacked the following:
- verification that the records were reviewed for accuracy,
  - documentation of each significant step in the manufacture, processing, or holding of the batch,
  - identification of major equipment used.
  - identification of each batch of component or in-process material used.
  - statement of the actual yield.
  - complete description of containers and closures.
  - sampling procedures.
- c) Failure to have batch production records reviewed and approved by a Quality Control unit to determine compliance with all established written procedures, before a batch is released or distributed.
- d) Failure to retain production, control, and distribution records for 3 years after distribution of the batch or at least one year after expiration date as applicable.

#### COMPONENTS:

- a) Failure to have, and implement, written procedures describing the receipt, identification, storage, handling, sampling, testing and approval or rejection of components and drug product containers and closures.

- b) Failure to validate the deionized water system, of which the deionized water is used as a component in the manufacture of drug products.

LABORATORY CONTROLS:

- a) Failure to test each batch of drug product for conformance to appropriate final specifications.
- b) Failure to test raw materials, used in manufacture of drug products, for conformity to purity, strength and/or quality specifications. There are no reports of raw material analysis (COAs) from the manufacturer for components used in drug products.
- c) Failure to establish and implement limits and types of objectionable microorganisms in the drug products.
- d) Failure to conduct microbiological tests on components and drug products that are liable to microbiological contamination.
- e) Failure to establish and implement a system to assure that reserve samples are maintained for active raw materials and finished drug products.

PACKAGING AND LABELING:

- a) Failure to have and implement written procedures describing the receipt, identification, storage, handling, sampling, examination and/or testing, and approval or rejection of labeling and packaging materials for drug products.
- b) Failure to have and implement procedures describing the controls employed for the issuance of labeling to assure correct labels are used for drug products.
- c) Failure to have and implement procedures to assure that OTC drug products meet requirements for temper-resistant package and labeling.

WAREHOUSING AND DISTRIBUTION:

- a) Failure to have and implement written procedures describing warehousing and distribution of drug products.
- b) Failure to have a system in place by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.

EQUIPMENT:

- a) Failure to have written cleaning procedures and maintain cleaning and maintenance records for major equipment used in the manufacture of drug products.

Phoenix Cosmetic Labs., Inc.

Page 4

- b) Failure to validate the cleaning of equipment (such as mixing tanks and filling lines) used in manufacture of drug products.
- c) Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals. For example, scales for weighing raw materials were not calibrated.

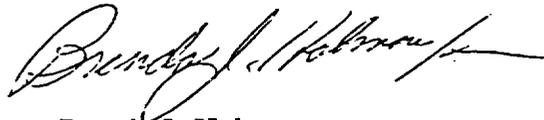
This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when 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 being initiated by the Food and Drug Administration without further notice. These actions include but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days after receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, N.Y. 11232, Attention: Fabio L. Mattiasich, Compliance Officer.

Sincerely,



Brenda J. Holmam  
District Director