



Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-82

September 7, 2001

Mr. Abelardo L. Acebo
President, Pharmakon Labs, Inc.
6050 Jet Port Industrial Blvd.
Tampa, FL 33634

Dear Mr. Acebo,

During an inspection of your facility located at the above address in Tampa, Florida, from June 6, 2001 to June 13, 2001, FDA Investigator Paul L. Figarole determined that you manufacture various over-the-counter and prescription products in liquid and tablet form, which products are human drugs within the meaning of section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

The product, Stagesic-10, is manufactured by your firm for [REDACTED]. The product contains Hydrocodone Bitartrate, a controlled substance, and is promoted in the package insert for moderate to moderately severe pain.

Based on the above claims this product, Stagesic-10, is a drug within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug, and Cosmetic Act, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drug.

Further, the article of drug, Stagesic-10, is misbranded in that its labeling fails to bear adequate directions for the use for which the article is represented or suggested (as described above), and it is not exempt from this requirement under regulation 21 CFR 201.115, since the article is a new drug within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for this drug.

The inspection also revealed several significant deficiencies from the Current Good Manufacturing Practice Regulations (GMP's) that cause all drugs manufactured by your firm to be adulterated within the meaning of section 501(a)(2)(B) of the Act, as follows:

Failure to establish qualification for manufacturing equipment and ancillary systems (i.e., air handling) or to perform any tests to verify the performance characteristics of the equipment.

Failure to validate or establish written procedures for the validation of equipment cleaning operations, water quality, or computer software used to calculate batch formulations.

Failure to perform or establish written procedures for process validations.

Failure to periodically monitor the quality of water used for manufacturing and cleaning.

Failure to establish a written GMP training program, or to document the on-the-job GMP training employees have received.

Failure to periodically audit the Certificates of Analyses received from component vendors to determine their reliability.

Failure to determine the reliability of outside labs performing finished product and stability testing.

Failure to perform and document annual reviews for each drug product or to document internal self-audits when performed.

On June 13, 2001, these deficiencies were listed on an FDA 483 and issued to and discussed with you. We have received your response to the FD-483 (Inspectional Observations), dated July 27, 2001. We cannot comment on the corrections because the letter does not list specific changes. We will evaluate any corrections at our next inspection.

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. It is further your responsibility as a contract manufacturer to assure that products you manufacture under contract have been reviewed and approved by the FDA, where such approval is required.

You should take prompt action to correct all 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. Federal agencies are advised of the issuance of all Warning Letters so that they may take this information into account when considering the award of contracts.

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, Florida District Office, 555 Winderley Place, Suite #200, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,



Emma R. Singleton
Director, Florida District