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September 27, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-57-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles B. Strauss, President
Unilever HPC-USA
33 Benedict Place
Greenwich, CT 06830

Dear Mr. Strauss:

An inspection of Conopco, Inc., 1657 N. Kilpatrick Ave., Chicago IL, a registered pharmaceutical manufacturer, was conducted from July 25-27, 2001. The inspection revealed significant deviations from Title 21, Code of Federal Regulations, (CFR) Parts 210 and 211. These deviations cause the pharmaceutical products manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to the following:

Failure of the building used in the manufacture, processing, packing, or holding of a drug product to be maintained in a clean and sanitary condition [21 CFR 211.56]. For example, our investigator observed live moth-like insects and roach-like insects in the compounding area. The investigator also observed open, unscreened windows in this area and a pool of standing water on the floor in the compounding area.

Failure to establish adequate written procedures that discuss the cleaning and maintenance of equipment [21 CFR 211.67]. For example, Conopco's procedures for cleaning the neuter batch tanks used in the production of pharmaceuticals fails to list the requirement that the tanks must sit for ■ hours after cleaning before the tanks can be utilized again.

Failure to maintain a written record of major equipment cleaning, maintenance and use [21 CFR 211.182].

Failure of laboratory testing records for raw materials and finished product, to indicate that a second person has reviewed the laboratory results for accuracy, completeness, and compliance with established standards [21 CFR 211.194(a)(8)].

Failure of batch production and control records to document that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188]. For example, the batch production records reviewed during this inspection failed to indicate that all steps of the manufacturing operation were completed because the operators failed to sign these records. Also, the batch records failed to indicate whether any sampling from the batch was performed.

At the conclusion of the inspection, a Form FDA-483, Inspectional Observations, was issued and discussed with Mark G. Wozniak, Plant Manager. A copy is enclosed for your information.

The above list of violations, as well as the Form FDA-483, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm is in compliance with the requirements of the Act and all applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to the attention of George F. Bailey, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Mark G. Wozniak, Plant Manager.
Conopco, Inc.
1657 N. Kilpatrick Ave.
Chicago IL