DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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# Warning Letter

VIA FEDERAL EXPRESS

WL# 320-00-03

April 10, 2000

Dr. Theo Burki
Labor Dr. Th. Burki
Gemeindezentrum
Muhen
Switzerland CH-5037

Dear Dr. Burki:

This is regarding an inspection of your microbiological testing laboratory in Muhen, Switzerland by Investigator Charles Edwards, of the United States Food and Drug Administration, on November 16, 1999. The inspection revealed significant deviations from U.S. current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. The deviations were presented to you on an Inspectional Observations form FDA-483 at the close of the inspection. These CGMP deviations may cause the drug products you test for pharmaceutical manufacturers to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Specific areas of concern include, but are not limited to:

1. Failure to control air filtration, uniform temperature distribution, or humidity control in the microbiological testing laboratory.

   a. There is no central heating, air-conditioning[ ]system in the laboratory.
   b. There are two unscreened and open windows in the area of the laboratory where bacterial media are poured into glass agar plates and allowed to solidify. The open windows could allow ambient air, contaminants and insects to enter the working area and compromise the sterile components and surfaces.
   c. The uncontrolled humidity level in the laboratory may compromise the stability of master strains of the microorganisms. During the inspection, the FDA investigator observed the thick coatings of ice at the freezer door

prevented the door being opened. The freezer had to be pried open using a screwdriver and other implements.

2. Inadequate training of laboratory personnel. The employees were observed to be month-pipetting.

3. Failure to record daily temperature for the incubators and refrigerators.

4. Inadequate written procedure (SOP) to specify clearly how to report out of specification (OOS) findings. Your Standard Operation Procedure [ ] covering out-of-specification results does not specify which results will be reported to [ ] if re-testing is performed.

The CGMP deviations identified above are not to be considered an all-inclusive list of the deficiencies at your facility. FDA inspections are audits which are not intended to determine all deviations from CGMPs that exist at a firm. We recommend that you evaluate your facility on an overall basis for CGMP compliance.

You should notify this office in writing, within 30 days of the receipt of this letter, of the specific steps you have taken or will take to address this concern. Until FDA has confirmed that your firm is in CGMP compliance, we will not recommend approval of any applications listing your firm as the microbiological testing laboratory.

If you have questions or concerns regarding this letter, please contact Brenda Uratani Ph.D., Compliance Officer, at the address and telephone numbers shown below:

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Sincerely,

Joseph C. Famulare
Director
Division of Manufacturing and Product
Quality, HFD-320