



DEPARTMENT OF HEALTH & HUMAN SERVICES

M753N

4/1/97
[Signature]

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

April 1, 1997

Ref: 97-DAL-WL-20

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Henry Rangel, President
Beta Dermaceuticals, Inc.
12014 Radium
San Antonio, Texas 78216

Dear Mr. Rangel:

During an inspection of your drug manufacturing facility in March, 1997, our investigator documented deficiencies from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). The deficiencies noted during the inspection cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

1. Failure to perform process validation on all drug products and related processes.
2. Failure to perform stability studies on all drug products.
3. Failure to conduct identification and minimum fill tests in accordance with the USP for Beta-HC lotion (1% and 1/4%) and cream (1/4%).
4. Failure to maintain written analytical test release specifications for the drug products manufactured and conduct chemical analysis on the purified water.
5. Failure to maintain written procedures for all drug operations, including the stability program, sampling of the bulk and finished drugs/purified water, the calibration of all equipment, cleaning of production equipment, complaint handling, raw material controls and handling of returned drug products.

Mr. Henry Rangel
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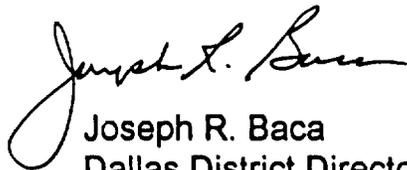
The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. A complete list of observations (FDA-483) was issued to you and discussed with you at the close of the inspection. It is your responsibility to assure that your facility is in compliance with all requirements of the federal regulations. Please address each deviation listed on the FDA-483 in your written response and not just the citations in this letter.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions may include seizure and/or injunction. You have previously been warned of these GMP deficiencies and promised correction both in writing and verbally during a meeting with a Dallas District representative on August 12, 1996.

You should notify this office in writing, within fifteen (15) working days, of receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. 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. You should immediately send a copy of this letter to your consultant and regulatory counsel if those relationships continue.

Your reply should be sent to the attention of Ms. Gwendolyn S. Gilbreath, Compliance Officer, at the above letterhead address.

Sincerely,



Joseph R. Baca
Dallas District Director

JRB:GSG