

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER:

11919 Rockville Pike (HFD-325)
Rockville, MD 20852
(301) 827-9012 Fax: (301) 827-8909

DATE(S) OF INSPECTION:

11/03/2003 - 11/10/2003

FBI NUMBER

3002806523

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Heinrich Scherfler, CEO

FIRM NAME

Sandoz GmbH

STREET ADDRESS

Biochemiestrasse 10

CITY, STATE, ZIP CODE, COUNTRY

6250 Kundl, Austria,

TYPE ESTABLISHMENT INSPECTED

Pharmaceutical and bulk drugs
manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been thoroughly distributed.

Specifically, the corrective actions implemented after the investigation of nine sterility failures reported since 2001 (3 for 2001, 3 for 2002 and 3 for 2003) for Posilac Injection or for the lyophilized active ingredient (Somatitrove Zinc) have not been effective in preventing reoccurrence. In five instances (2 for 2001, 1 for 2002 and 2 for 2003) the organism was identified as *Propionibacterium acnes*; *Staphylococcus* species have been identified in three instances and in one instance (in 2002) *Bacillus pumilus* was found. *Propionibacterium* was found in environmental samples of the manufacturing areas, in the equipment and in one of the raw materials; *Bacillus pumilus* was found repeatedly in environmental samples of the manufacturing areas. Batches manufactured around the same period of time and under the same conditions of the affected lots have been released to the market.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 2

Equipment for adequate control over micro-organisms is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, handling of the trays used to lyophilize the Somatitrove Zinc and the bowls used to feed empty syringes and plungers to the two filling lines used for Posilac Injection is not adequate to prevent their re-contamination after sterilization. Although the lyophilizer trays are product-contact surfaces and the bowls are in contact with product containers, these are transported after sterilization through areas that have been classified by the firm as Class B.

**SEE REVERSE
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LABORATORY CONTROLS SYSTEM

OBSERVATION 3

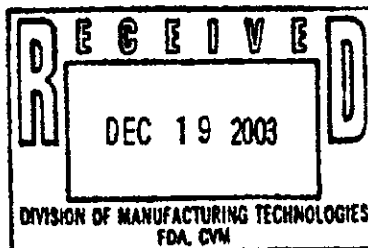
Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically, reserve samples of only three lots of are examined visually once a year. There are no statistical procedures to select a representative sample of lots of drug products for visual examination.

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Rebecca Rodriguez

Rebecca Rodriguez, Investigator



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OF THIS PAGE

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