



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
Foreign Inspection Team, HFD-325
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November 15, 2007

Mr. Gunther Rasack,
Managing Director
Gesellschaft für Micronisierung mbH
Lesumer Heerstrasse 30
Bremen,
Germany, Federal Republic of

Dear Mr. Rasack:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your pharmaceutical manufacturing facility in Bremen, Germany, during July 19 & 20, 2007 by Investigator Kevin A. Gonzalez, and Chemist Felix Maldonado. An Inspectional Observations form FDA-483 was issued to you at the conclusion of that inspection.

We have reviewed your October 10, 2007 response letter to the Inspectional Observations form FDA-483 that was issued on July 20, 2007. Based on the corrections described in the response, we are classifying your facility as acceptable. It remains your responsibility to assure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.

Since the Agency is working to make its regulatory process and activities more transparent to the regulated industry, enclosed is a copy of the Establishment Inspection Report (EIR) for the above inspection. The enclosed copy contains only the narrative portion of the report. However, you may request additional information under the Freedom of Information Act.

If you have any questions concerning this letter, you may contact me at the above address or telephone numbers.

Sincerely,

Edwin Melendez
Consumer Safety Officer

Enclosure: