



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
11919 Rockville Pike, MM2
Rockville, MD 20852

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September 28, 2007

Horst Meyer
Vice President Chemical Division
W.C. Heraeus GmbH
Heraeusstrasse 12-14
63450 Hanau
Germany

Dear Dr. Meyer:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient manufacturing facility in Hanau, Germany by FDA Investigator Joey V. Quitania and Chemist Tina M. Pawlowski. A FDA 483, Notice of Inspectional Observations was issued to you at the conclusion of that inspection.

We have also reviewed the August 7, 2007 written response to the FDA 483 observation. Based on the corrections described in the response, we are classifying your facility as acceptable. The corrective actions will be further evaluated during the next routine inspection of this facility. It remains your responsibility to assure continued compliance with 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.

You may contact me at Montrose Metro II, 11919 Rockville Pike, Rockville, MD 20852.
You may also contact my office by telephone at (301)827-9073 or by fax at (301)827-8909.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony A. Charity". The signature is written in a cursive style with a large initial "A".

Anthony A. Charity,
Compliance Officer
Foreign Inspection Team, HFD-325

Enclosure: