



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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June 21, 2006

Mr. Marco Falciani
President
ACS Dobfar
Viale Addetta 4/12
20067 Tribiano
Milan
Italy

Dear Mr. Falciani:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Tribiano, Milan, Italy on March 20-29, 2006 by Investigator Thomas Arista, and Chemist Cynthia Lee. A FDA-483, Notice of Inspectional Observations was issued to you at the conclusion of that inspection.

We have reviewed your April 28, 2006 written response to the FDA-483 observations. 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.

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,

Carole L. Jones
Compliance Officer
Foreign Inspection Team, HFD-325

Enclosure