



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

TELEPHONE: (301) 827-9021
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November 30, 2004

Marco Falciani
President
ACS Dobfar
Viale Addetto, 2/12
20067 Tribiano, Milano
Italy

Dear Mr. Falciani:

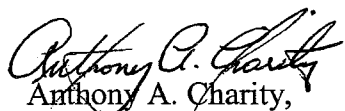
We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient facility in Anagni, Italy on September 20-23, 2004 by FDA Investigator Azza Talaat. A FDA-483, Notice of Inspectional Observation was issued to you at the conclusion of that inspection.

We have also reviewed the October 7, 2004 written response letter to the FDA-483 observations. 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 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.

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,



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

Enclosure: