



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

G 003-095-K0000

ACS Dobfar S.p.A.
Attention: Mr. Marco Falciani
President
Viale Addetta, 4/12
20067 Tribiano
Milano, Italy

JUN 2 2004

Dear Mr. Falciani:

We refer to the September 30 – October 2, 2003, inspection of your pharmaceutical manufacturing facility at ACS Dobfar S.p.A. at the Albano Plant, Italy by FDA Investigator Stephen D. Brown. The inspection revealed cGMP deficiencies which were issued to you on Form FDA-483 at the conclusion of the inspection.

We have reviewed your November 10, 2003, and May 13, 2004, responses to the FDA-483 observations. Based on the additional information submitted, your facility has been classified as acceptable. According to your response, corrections to all FDA-483 observations have been implemented. We remind you that it is your responsibility to assure continued compliance to 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 FOIA. If you have questions regarding the enclosed EIR, please contact me at (301) 827-6462.

Sincerely yours,

Michael J. Popek
Acting Team Leader
Antimicrobial Team
Division of Manufacturing Technologies
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure