



G 002-933-K0001

ACS Dobfar SpA

• Attention: Mr. Marco Falciani  
President  
Viale Addetta, 4/12  
20067 Tribiano  
Milano, Italy

JAN 17 2006

Dear Mr. Falciani:

We refer to the October 31 – November 7, 2005, inspection of your pharmaceutical manufacturing facility located at ACS Dobfar SpA, Via Rossini, 9/11 20067 Tribiano, Milan, Italy by FDA Investigator Melissa J. Garcia and Microbiologist Barbara D. Paul. The inspection revealed cGMP deficiencies which were issued to you on Form FDA-483 at the conclusion of the inspection.

We have reviewed your December 8, 2005, response 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) 827-6964.

Sincerely,

Mai X. Huynh  
Team Leader  
Antimicrobial Team  
Division of Manufacturing Technologies  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

Enclosure