



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

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Division of Manufacturing and Product Quality  
Foreign Inspection Team, HFD-325  
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April 16, 2007

Dr. Sergio Dusci, Managing Director  
ACS Dobfar Info SA  
CH-7748 Campascio  
Switzerland

Dear Dr. Dusci:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Campascio, Switzerland on February 12-15, 2007 by FDA Investigator Caryn M. McNab and Microbiologist Susan M. Jackson. We are classifying your facility as acceptable as a sterile pharmaceutical. However, it remains your responsibility to assure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.