



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
International Compliance Branch
10903 New Hampshire Avenue
Building #51, Room 4242
Silver Spring, MD 20993

TELEPHONE: (301) 796-3193
FAX: (301) 847-8742

September 25, 2009

Dr. Joseph Carulla, Director
Inke
Area Industrial del Liobregal
C/Argent, 1
08755 Castellbisbal
Barcelona, Spain

Dear Dr. Carulla:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Barcelona, Spain by Investigator Azza Talaat on July 20-25, 2009. A FDA-483, Inspectional Observations, was issued at the conclusion of the inspection.

We have also reviewed your company's response dated July 13, 2009 with supportive documentation. Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMPs).

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Thomas S. Savage
Compliance Officer
International Compliance Team

Enclosure