



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Quality Surveillance Assessment  
Inspection Assessment Branch  
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July 23, 2015

Mr. Angelo Caccamo  
President  
Beltapharm S.p.A.  
Viale Stelvio 66  
Cusano Milanino  
Milano 20095  
Italy

Reference FEI: 3009853808  
Reference inspection date: May 11-15, 2015  
Establishment Locale: Milano, Italy

Dear Mr. Caccamo:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at the above address or number.

Sincerely,

Rebecca Frey-Cooper, PHD  
Chemist  
Inspection Assessment Branch

Enclosure: EIR