



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
10903 New Hampshire Avenue
Building #51, Room 4316
Silver Spring, MD 20993

TELEPHONE: 301-796-3254
FAX: (301) 847-8742

March 22, 2016

Mr. Antoine Balland Pharm. D,
Managing Director
Eurofins Pharma Quality control
9 Avenue de Laponie
Les Ulis,
F-91967 Courtaboeuf Cedex
France

Reference FEI 3007602003
Reference inspection date (s): 12/04/2015-12/08/2015
Establishment Locale: France

Dear Mr. Antoine Balland,

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,

Jeneen Huff-Roh
Concepcion Cruz for.

Branch Chief
Inspection Assessment Branch

Enclosure: EIR