



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR VETERINARY MEDICINE

Office of Surveillance and Compliance
Division of Compliance, HFV-230
Post-Market Compliance Team
7519 Standish Place
Rockville, MD 20855

February 28, 2017

Mr. Paul Moran, Owner and Chief Executive
Broughton Laboratories Ltd.
Coleby House, The Watermill Park, Broughton Hall
Skipton, North Yorkshire, BD23 3AG, UK

Reference: Inspection Date(s): 7/11/16 – 7/14/16
Location: Broughton Laboratories Ltd.
Coleby House, Broughton Hall; The Water Mill Park
Skipton, North Yorkshire, BD23 3AG
United Kingdom
FEI: 3008408212

Dear Mr. Paul Moran,

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 Marea.Harmon@fda.hhs.gov.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Marea Harmon
Consumer Safety Officer

Enclosure: Establishment Inspection Report (EIR)