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
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February 22, 2016

Dr. Frederic Girard and Dr. Flore Le Grand
Managing Director & QA Manager
Spinnovation Analytical BV
Molensstraat 110, 5342 CC
Oss, Netherlands

Reference FEI 3011521858
Reference inspection date (s): 11/19/2015 - 11/20/2015
Establishment Locale: Netherlands

Dear Dr. Frederic Girard and Dr. Flore Le Grand:

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,
Rhoda B. Eniafe -S

Digitally signed by Rhoda B. Eniafe -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010069587, cn=Rhoda B. Eniafe -S
Date: 2016.02.22 09:48:01 -05'00'

Rhoda Eniafe
Consumer Safety Officer
Inspection Assessment Branch

Enclosure: EIR

[redacted]

REFUSALS

There were no refusals

GENERAL DISCUSSION WITH MANAGEMENT

An inspection closing meeting was held which consisted of the following individuals:

- Dr. Ruud Santing PhD., CEO
- Dr. Frederic Girard PhD; Managing Director
- Dr. Flore Le Grand, QA Manager

During the closing meeting, form FDA 483, Inspectional Observations, was not issued to the firm.

ADDITIONAL INFORMATION

[redacted]

EXHIBITS COLLECTED

1. FDA registration.
2. Corporate Management Structure.
3. [redacted]

ATTACHMENTS

1. FACTS assignment (three pages)