

Public Health Service Food and Drug Administration New York District 158-15 Liberty Avenue Jamaica, NY 11433 Telephone (718) 340-7000

April 6, 2016

Dr. Govind S. Gill, Owner American Hormones, Inc. 69 W. Cedar St. Poughkeepsie, NY 12601-1351

Dear Dr. Gill,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, American Hormones, Inc., located at 69 W. Cedar Street, Poughkeepsie, NY 12601-1351, from January 7, 2015 to January 9, 2015, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 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 for 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 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining additional information under FOIA.

The letter is not intended as an endorsement or certification of your facility. It remains your responsibility to assure continued compliance with the requirements of federal law, including FDA regulations.

If there is any question about the released information, please contact CDR Frank Verni, Compliance Officer at (718) 662-5702 or at frank.verni@fda.hhs.gov or write to:

U.S. Food and Drug Administration New York District Office Attn: CDR Frank Verni, Compliance Officer 158-15 Liberty Ave. Jamaica, NY 11433 Sincerely,

Ronald Pace

Director, New York District Office

Enclosure: EIR