

Atlanta District 60 8th Street, NE Atlanta, Georgia 30309

Tel: 404.253.2282 Fax: 404.253.1202

December 30, 2016

Shawn E. Hodges, Pharm.D. Owner Innovation Compounding, Inc. 6095 Pine Mountain Road NW, Suite 108 Kennesaw, GA 30152-3332

Dear Dr. Hodges:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Innovation Compounding, Inc., located at 6095 Pine Mountain Road NW, Suite 108, Kennesaw, GA 30152-3332, from February 1, 2016, to June 9, 2016, by the U.S. Food and Drug Administration (FDA).

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

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.

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 any additional information under FOIA.

If there is any question about the released information, please contact Janice L. King, 843-746-2990, x16 or by email at Janice.King@fda.hhs.gov.

Since

Ingrid A. Zambrana District Director Atlanta District Office Southeast Region, Office of Regulatory Affairs U.S. Food & Drug Administration

Enclosure: EIR