



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Ste. 200
Maitland, Florida 32751

Telephone: (407) 475-4700
FAX: (407) 475-4769

July 21, 2016

Jessica E. Dileo, Pharm.D., Owner
Custom Meds, Inc.
102 E. Highland Blvd.
Inverness, FL 34452-4847

Dear Dr. Dileo:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Custom Meds, Inc., located at 102 E. Highland Blvd., Inverness, FL 34452-4847, from March 22, 2016, to March 25, 2016, 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.

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.

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.

If there is any question about the released information, please contact, Andrea H. Norwood, Compliance Officer, at (407) 475-4724 or Andrea.Norwood@fda.hhs.gov or write to:

U.S. Food and Drug Administration
Florida District Office
555 Winderley Place, Suite 200
Maitland, FL 32751

Sincerely,

A handwritten signature in blue ink that reads "Susan M. Turcovski".

Susan Turcovski
Florida District Director

Enclosure: EIR