

U.S. Food and Drug Administration Division of Pharmaceutical Quality Operations III 300 River Place, Suite 5900 Detroit, MI 48207 Telephone: (313) 393-8100

Fax: (313) 393-8139 www.fda.gov

February 11, 2019

UPS NEXT DAY SIGNATURE REQUIRED

Brian Griffin Chairman and CEO Diplomat Pharmacy Inc. dba Diplomat Specialty Pharmacy 4100 S Saginaw Street Flint, MI 48507-2687

Dear Mr. Griffin:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Diplomat Pharmacy Inc. dba Diplomat Specialty Pharmacy, located at 4100 South Saginaw Street, Flint, MI 48507-2687, from October 31, 2017, to November 17, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Michigan State Board of Pharmacy for follow up.

When the Agency considers an inspection to be "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 Russell Riley, Compliance Officer, at (630) 323-2763 ext. 101, or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Lyons -S

Nicholas F. Digitally signed by Nicholas F. Lyons -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=130012003 3, cn=Nicholas F. Lyons -S Date: 2019.02.11 11:52:45 -06'00'

Nicholas F. Lyons Compliance Director Division of Pharmaceutical Quality Operations III

Enclosure: EIR and State Referral Letter

FMD-145 Cover Letter only cc:

> Cheryl Wykoff Pezon Michigan State Board of Pharmacy Bureau of Professional Licensing/Licensing Division 611 W. Ottawa, 3rd Floor P.O. Box 30670 Lansing, MI 48909-8170