



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
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April 23, 2020

VIA ELECTRONIC MAIL

Mr. Douglas L. Dumler
General Manager
Option Care Enterprises, Inc.
9140 Guilford Road, Suite K
Columbia, MD 21046-1811

FEI: 3012335395

Dear Mr. Dumler:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Option Care Enterprises, Inc., dba Option Care, located at 9140 Guilford Road, Suite K, Columbia, MD 21046-1811, from June 20, 2016, to June 28, 2016, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Maryland 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 you have any questions, contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or 518-453-2314 X-1014.

Office of Pharmaceutical Quality Operations

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Detroit, MI 48207
Telephone: (313) 393-8100

Pharmaceutical Division IV
19701 Fairchild Rd.
Irvine, CA 92612
Telephone: (949) 797-1063

Please send electronic inquiries to orapharm1_responses@fda.hhs.gov. Please identify your response with FEI: 3012335395.

Stephanie
T. Durso -S

Digitally signed by Stephanie T. Durso -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300194209, cn=Stephanie T. Durso -S
Date: 2020.04.23 07:50:17 -04'00'

Stephanie Durso
Director Compliance Branch
U.S. Food and Drug Administration
OPQO Division I / New Jersey District

Enclosure: EIR and SRL

Cc: Maryland State Board of Pharmacy (cover letter only)
P.O. Box 1991
Baltimore, MD 21203