DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

July 08, 2020

John J. Coleman
(b) (6)
[redacted]

Sent via email to: (b) (6) [redacted]

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to amend the label for Epidiolex®, specifically, the language in subparagraph 9.1 of the label that states "EPIDIOLEX is not a controlled substance", to correctly and accurately that "EPIDIOLEX is a Schedule V controlled substance" was received by this office on 07/08/2020.

It was assigned docket number FDA-2020-P-1641. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.07.08 11:49:35 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)