



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 24, 2019

Samuel A. Gonzalez

(b) (6)

Sent via email to: (b) (6)

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to Amend CFR Title 21 101.36 b ii 2 was received by this office on 09/24/2019.

It was assigned docket number FDA-2019-P-4448. 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 Bigby
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)