DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 30, 2019

Vincent Canzanese Rph
Summit Health Pharmacy Inc.
3400 Edgmont Ave
Brookhaven, PA 19014

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner amend the regulation 21 CFR § 216.23 (bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act) to include oxitriptan on the 503A Bulks List and to allow continued compomding of oxitriptan for the treatment oftetrahydrobiopterin deficiency diseases in the interim was received by this office on 04/30/2019.

It was assigned docket number FDA-2019-P-2088. 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

Digitally signed by
Dynna Bigby
Date: 2019.05.01
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Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office Operations (OO)