



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

November 7, 2019

James Grote

(b) (6)

Sent via email: (b) (6)

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the Commissioner to disclose whether listed drugs ANDA 040063, ANDA 088606 and ANDA 084476 have been voluntarily withdrawn or were withdrawn for safety or effectiveness reasons was received by this office on 11/07/2019.

It was assigned docket number FDA-2019-P-5266. 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,

Karen Malvin  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)