



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 6, 2019

Dhananjay Barot
Aavis Pharmaceuticals
9488 Jackson Trail Rd
Hoschton, GA 30548

Sent via email to: dbarot@aavispharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine that new drug combination of Chlorzoxazone and Acetaminophen in tablets dosage form is suitable for submission in an Abbreviated New Drug Application was received by this office on 12/06/2019.

It was assigned docket number FDA-2019-P-5759. 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 Officer
Dockets Management Staff
Food and Drug Administration
OC/OO/OEMS/DIG