



Anthony LaViola
Principal Consultant
Pharmobedient Consulting, LLC
642 N.E. 3rd Ave.
Fort Lauderdale, FL 33304

August 16, 2024

Re: Docket No. FDA-2024-P-0761

Dear Mr. LaViola:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 21, 2024. Your petition requests that the Agency determine whether Tavist (clemastine fumarate) tablets, 2.68 milligrams, new drug application 017661, was withdrawn from sale for safety or effectiveness reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett

Date: 2024.08.16 09:52:58 -04'00'

Carol J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research