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

October 18, 2024

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

Dear Mr. LaViola:

This letter responds to your citizen petition received on February 21, 2024, requesting that the Food and Drug Administration (FDA) determine whether TAVIST (clemastine fumarate) tablet, 2.68 milligrams (mg), under the new drug application 017661 held by Novartis Pharmaceuticals Corp., was voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that TAVIST (clemastine fumarate) tablet, 2.68 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain TAVIST (clemastine fumarate) tablet, 2.68 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-0110.

Sincerely,

Awo Archampong-gray -S

Digitally signed by Awo Archampong-gray -S
Date: 2024.10.18 12:51:03 -04'00'

Awo Archampong-Gray
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure