U.S. FOOD & DRUG ADMINISTRATION

Neal Parker
Raymond C. Votzmeyer
AbbVie Inc.
1700 Rockville Pike #500
Rockville, MD 20852

September 19, 2024

Re: Docket No. FDA-2024-P-1715

Dear Petitioner:

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 April 3, 2024. Your petition requests that the Agency "prohibit manufacturers who lack active investigational new drug applications (INDs) and robust clinical development programs from commercializing unlicensed DTE [desiccated thyroid extract] products." You further requested that the FDA "stop DTE manufacturers from promoting and making false and misleading statements about their unlicensed products."

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 J Bennett

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

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