November 16, 2022

Lemrey “Al” Carter, MS, PharmD, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Dr
Mount Prospect, IL 60056
acarter@nabp.pharmacy

Dear Dr. Carter:

Following issuance of our letter to NABP on Sept. 16, 2022, regarding desiccated thyroid extract (DTE) products that appear to have been prepared by state-licensed pharmacies, FDA has been contacted by stakeholders expressing concerns about access to DTE products. We understand that many Americans take medication to treat hypothyroidism, and some choose to take DTE products to treat their medical condition.

DTE products continue to be available, and FDA intends to make any additional information regarding DTE products available to the public. While the Agency continues to address any complaints related to DTE products prepared by state-licensed pharmacies, we have not to date taken steps more generally to remove products prepared by drug compounders containing DTE or limit compounder access to DTE. The agency recognizes our activities are of great interest to a wide range of stakeholders.

As stated in FDA’s guidance document, “Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act,” generally, FDA expects to employ a risk-based enforcement approach with respect to violative compounded drugs, giving the highest enforcement priority to compounded drugs and violations of the Federal Food, Drug, and Cosmetic Act and FDA regulations that pose the greatest public health risks, such as serious adverse events or serious product quality or adulteration issues.

Sincerely,

Frances G. Bormel -S

Digitally signed by Frances G. Bormel -S
Date: 2022.11.16 12:10:50 -05'00'

F. Gail Bormel, RPh, JD
Director, Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research