NABP
National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: September 22, 2022

RE: FDA Letter Regarding Desiccated Thyroid Extract Preparations

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The Food and Drug Administration (FDA) has become aware of desiccated thyroid extract (DTE) that appears to have been prepared by state-licensed pharmacies being offered to patients. FDA has issued the attached letter to NABP and asked that it be shared with our member boards.

States that wish to provide information to FDA should submit the information by email to the following mailbox: compounding@fda.hhs.gov.

Attachment

cc: NABP Executive Committee

U.S. FOOD & DRUG ADMINISTRATION

September 16, 2022

Lemrey "Al" Carter, MS, PharmD, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Dr
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acarter@NABP.pharmacy

Dear Dr. Carter:

The purpose of this letter is to bring to the attention of the National Association of Boards of Pharmacy (NABP) that the Food and Drug Administration (FDA) is aware of desiccated thyroid extract (DTE) that appears to have been prepared by state-licensed pharmacies being offered to patients. These products can put patients at harm. We encourage you to share this information with your members.

There are two types of thyroid replacement therapies: (1) synthetic therapies containing only levothyroxine or liothyronine; and (2) therapies made from DTE, which is produced from dried ground animal thyroid glands. DTE is sold in the United States as Armour Thyroid, NP Thyroid, Nature-Throid, and Natural Thyroid, among other names.

While synthetic thyroid replacement therapies containing only levothyroxine or liothyronine are drugs subject to approval under the Federal Food, Drug, and Cosmetic Act (FD&C Act), therapies containing DTE are biological products subject to licensure under section 351 of the Public Health Service Act (PHS Act).

DTE products meet the definition of a "biological product" under section 351(i) of the PHS Act (21 U.S.C. § 262(i)). Under that definition, a "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, *protein, or analogous product*, . . . applicable to the prevention, treatment, or cure of a disease or condition in human beings." 21 U.S.C. § 262(i)(1) (emphasis added). FDA's regulations define the term "protein" in the statutory definition of "biological product" to mean "any alpha amino acid polymer with a specific, defined sequence that is *greater* than 40 amino acids in size" (see 21 CFR 600.3(h)(6); see also 85 FR 10057). DTE meets the definition of a biological product because it is a "protein" or "analogous" to a protein. DTE is derived from animal thyroid glands (usually porcine, meaning from a pig) and necessarily contains thyroglobulin, an alpha amino acid polymer with a specific defined sequence, consisting of 2,770 amino acids.

Section 351(a)(1) of the PHS Act prohibits the introduction into interstate commerce of any biological product unless "a biologics license . . . is in effect for the biological product." Biological products subject to licensure under section 351 of the PHS Act are not eligible for the exemptions for compounded drug products under sections 503A and 503B of the FD&C Act.

FDA has not approved any biologics license applications (BLAs) for DTE products. Some biological products, including thyroglobulin products, had historically been approved under section 505 of the FD&C Act (21 U.S.C. § 355). However, the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) required that as of March 23, 2020, all sponsors seeking approval of a biological product that previously could have been submitted under section 505 of the FD&C Act (21 U.S.C. § 355) must submit a BLA under section 351 of the PHS Act (42 U.S.C. § 262).

In addition, unlicensed DTE products have not been reviewed by the FDA to ensure safety, purity, and potency, and therefore may present issues with respect to quality and dosing, among other things. For example, tablets made from the same batches may not always have the same hormone levels. Inconsistent dosage can have serious consequences for patients; too much medication can cause bad side effects, and too little can be ineffective. As a reminder, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products, because these compounders are not licensed by FDA and generally do not register their facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint. Recently, FDA has received complaints related to the safety, purity, and potency of unlicensed DTE products that appear to have been prepared by state-licensed pharmacies.

We advise that you encourage state boards of pharmacy to submit to FDA any concerns or questions involving the preparation of biological products, including DTE, outside the scope of an approved BLA. States that wish to provide this information to FDA should submit the information by email to the following mailbox: compounding@fda.hhs.gov.

We are also sending this letter to the Federation of State Medical Boards to facilitate communication among associations with shared goals regarding these matters.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We look forward to continuing to work with you on matters related to human drug compounding. If you have additional questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

Shannon Glueck, PharmD
Branch Chief
Branch 4
Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research