

ISSUE BRIEF:

FDA restricts thyroid compounding options

Via a series of communications with the National Association of Boards of Pharmacy, FDA has declared desiccated thyroid extract (DTE) to be a biologic drug and therefore ineligible for compounding. DTE is sold in the United States as Armour Thyroid, NP Thyroid, Nature-Throid, and Natural Thyroid, among other names. Thyroid USP is the source of levothyroxine and liothyronine in these products and in compounded preparations.

The FDA sent a September 26, 2022, letter to the National Association of Boards of Pharmacy in which the FDA proclaims that therapies containing desiccated thyroid extract (DTE) are biological products subject to licensure under section 351 of the Public Health Service Act (PHS Act). That letter created significant confusion among compounders and state boards of pharmacy. As a result, the agency followed up with a November 16, 2022, letter to NABP indicating that the agency would not prioritize disciplinary action against compounding pharmacies that prepared and dispensed compounded DTE. The letter stopped short of recommending that state boards of pharmacy adopt a similar approach.

Unlike the transparency that FDA provided in its publication of the List of Approved NDAs for Biological Products That Were Deemed to be BLAs on March 23, 2020 – including multiple public comment periods on issues surrounding FDA’s transition of drug products to biologics and FDA’s interpretation of what is considered a biologic – no such public process was followed here. Instead, the FDA sent a letter to NABP to be distributed to its state counterparts announcing a new policy to the effect of “compounding DTE products is a violation of law.” In turn, the pharmaceutical supply chain, which provides millions of patients in America necessary medications, ceased providing DTE to compounders for fear of state or federal action. In response to becoming aware of the letter’s effect, FDA sent another letter to the same stakeholders asserting that DTE products continue to be available.

Our primary concerns:

- DTE is not a biologic because the active ingredient does not meet the definition of a biologic product. FDA asserts that a drug product that contains a protein only as an inactive ingredient is not considered to be a “protein” for purposes of the statutory definition of “biological product.”
- FDA incorrectly categorizes DTE as a biologic product. the labeling of currently marketed DTE commercial products does not identify or quantify thyroglobulin as a component. Any amounts of thyroglobulin potentially contained in DTE should be considered an inactive ingredient because thyroglobulin is not intended to furnish pharmacological activity
- A statutory authority exists for licensed pharmacists and licensed physicians to compound drug products using bulk drug substances that comply with the standards of the USP monograph for Thyroid USP. FDA must immediately clarify to State Boards of Pharmacy that compounding using Thyroid USP is a permissible activity.

In short, the concern is that FDA is implementing a sort of back-door restriction of compounded DTE that is problematic in its rationale and is communicating it by a novel approach – a letter from a CDER branch chief to the association of state boards of pharmacy – rather than a definitive industry communication. The potential impact of this action on patients stands to be severe.

In December 2022, APC submitted a comment letter to the FDA docket outlining these concerns. For the time being, we urge state boards of pharmacy to adopt a position similar to that FDA announced in its second letter (November) to NABP, which amounts to “enforcement discretion.”