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Alliance for Pharmacy Compounding

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July 2, 2026

Kyle A. Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Urgent need for continued enforcement discretion and transition guidance for desiccated thyroid extract products

Dear Acting Commissioner Diamantas:

On behalf of the Alliance for Pharmacy Compounding, I am writing with urgency about desiccated thyroid extract products and the very real supply-chain and patient-access issues we believe are likely to worsen as FDA's current enforcement-discretion period approaches its end.

APC is the national trade association representing the pharmacy compounding profession, including more than 600 compounding small businesses and the pharmacists, technicians, and professionals who serve patients whose clinical needs cannot be fully met by FDA-approved drug products. Our members work every day with prescribers and patients to prepare medications pursuant to patient-specific prescriptions under section 503A of the Federal Food, Drug, and Cosmetic Act, and they are often among the first to see the practical effects of regulatory uncertainty on patient care.

As FDA knows, a significant number of patients rely on DTE products because they and their prescribers have determined that levothyroxine and liothyronine products do not adequately meet their clinical needs. Whatever one's view of the regulatory history of these products, the practical reality is that these are not fringe therapies for the patients who depend on them. For many, DTE products are the therapy that has allowed them to feel stable, functional, and well-managed.

Our concern is that, absent continued agency enforcement discretion, patients may face abrupt disruption in access before there is a realistic approved-product pathway in place. That disruption would not be theoretical. Pharmacies, prescribers, patients, manufacturers, suppliers, and state boards of pharmacy are already asking what happens next – and no one seems to know the answer. Indeed, some boards of pharmacy have reached out to APC directly with questions for us about FDA's position and the implications for state oversight, pharmacy practice, and patient access.

That uncertainty is compounded by the unusual intersection of this issue between CDER and CBER. DTE products have long been understood and used in clinical practice as thyroid drug products. FDA's more recent position that these animal-derived thyroid products are regulated as biological products creates practical confusion for stakeholders who are trying to understand which regulatory pathway applies, which center is leading the transition, and what pharmacies, prescribers, suppliers, and state regulators should expect during the interim period.

Manufacturers and suppliers are likewise facing uncertainty about whether they can continue to produce and supply product while an NDA, BLA, or other appropriate marketing-application pathway is pursued.

The result is already a narrowing of supply, prescriber confusion, patient anxiety, and – most concerning – the potential for forced therapeutic changes for patients who are presently stable. Notwithstanding this, if FDA were to instead pursue approval of DTE as a drug product, patients and the profession would not have these access concerns.

APC recognizes and respects FDA's interest in bringing regulatory clarity to this category. But we also believe patient continuity of care must be a central part of that transition. If FDA's objective is to move these products toward approval, the agency should also ensure there is a workable bridge that prevents avoidable patient harm while that process unfolds.

For that reason, we respectfully urge FDA to provide guidance or a public clarification indicating that the agency will maintain continued enforcement discretion for DTE products until an NDA, BLA, or other appropriate marketing application is granted – or at least until there is a clear, practical, and patient-protective transition pathway in place. Such guidance would give pharmacies, prescribers, suppliers, state boards of pharmacy, and patients needed clarity and would help prevent unnecessary disruption in care.

We also urge FDA to make clear how CDER and CBER are coordinating on this issue, which center or office will serve as the principal point of contact for stakeholder questions, and how the agency intends to address the practical supply-chain and patient-access consequences of any change in enforcement posture.

APC would welcome the opportunity to meet with FDA, including appropriate staff from both CDER and CBER, to share what we are hearing from pharmacies, prescribers, patients, suppliers, and boards of pharmacy, and to discuss how FDA might structure a transition that serves both regulatory objectives and patient access.

Thank you for your consideration and for FDA's attention to the patients who may be affected by this transition.

Respectfully,

R. Scott Brunner, CAE
Chief Executive Officer