



**VIA EMAIL**

March 11, 2026

Dear Manufacturers, Importers, and Distributors of Animal-Derived Thyroid (ADT) Products:

As stated in the Agency's August 6, 2025 letter, "FDA intends to provide adequate time to transition patients to an FDA-approved thyroid hormone replacement product before initiating action against manufacturers, distributors, and importers of ADT and unapproved ADT products intended for commercial distribution. During this time, FDA will continue to apply a risk-based enforcement policy."

Under FDA's current policy, FDA is applying its general, risk-based enforcement approach to unapproved ADT products, giving enforcement priority to drugs that pose the highest risk to public health.

FDA plans to issue draft guidance before August 2026 that describes the Agency's compliance priorities and conditions of continued enforcement discretion for marketed unapproved ADT products. This draft guidance will be issued consistent with good guidance practices. FDA also intends to simultaneously publish a draft guidance regarding the development of ADT products to support submission of marketing applications.

FDA is committed to ensuring patient safety for those patients currently using unapproved ADT products while firms seek approval of marketing applications for ADT products.

If you have any questions related to this notice, please contact [FDAADVISORY@fda.hhs.gov](mailto:FDAADVISORY@fda.hhs.gov), and include your firm name and the unique identifier "XXXXXX" in the subject line of the email.

Sincerely,

U.S. Food and Drug Administration