VIA EMAIL

August 5, 2026

NAME
FIRM
ADDRESS
EMAIL

RE: [CMS Number]

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

On March 11, 2026, FDA issued a notice to manufacturers, importers, and distributers of ADT products that stated, "FDA plans to issue draft guidance before August 2026 that describes the Agency's compliance priorities and conditions of continued enforcement discretion for marketed unapproved ADT products." In that notice, FDA also stated its intent to simultaneously publish a draft guidance regarding the development of ADT products to support submission of marketing applications.

The Agency continues its work to complete these draft guidances. In the interim, FDA will continue applying its general, risk-based enforcement approach to unapproved ADT products, giving enforcement priority to products that pose the highest risk to public health. FDA remains 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, and include your firm name and the unique identifier "_____" in the subject line of the email.

Sincerely,

U.S. Food and Drug Administration

DRAFT

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