



Genzyme Corporation

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November 11, 2009

RE: Reports of Foreign Particles in Thyrogen[®] (thyrotropin alfa for injection)

Dear Health Care Practitioner,

Genzyme has detected foreign particles in some products filled at the Allston Landing facility in the course of routine quality control. Genzyme has also received customer reports of foreign particles in some vials of these products. The particles observed include non-latex rubber originating from the stopper, or stainless steel particles or fiber-like material originating from the manufacturing process. To help ensure that patients are not exposed to foreign particles during product administration, we are writing to alert health care practitioners of the potential presence of such foreign particles and reinforce recommendations consistent with the approved product labeling for product preparation and administration.

Foreign particles identified by visual inspection prior to administration ranged in size from 140-295 microns. Intramuscular injection of foreign particles of this size may cause local reactions at the site of injection. These include injection site reactions such as pain, local swelling and foreign body granuloma as well as local allergic reactions including rash and urticaria.

To better understand these potential risks to patients, Genzyme has reviewed the Thyrogen global safety database which contains all adverse events reported to Genzyme from January 2004 through 5 Nov 2009 and did not identify any safety concerns that could be potentially related to intramuscular injection of foreign particles.

We are providing the following recommendations for Thyrogen:

1. Perform a visual examination of the lyophilized product prior to reconstitution. **Do not use if there are foreign particles.**
2. Follow the preparation instructions provided in the Dosage and Administration section of the approved product labeling.
3. As stated in the approved product labeling, visually inspect the reconstituted product for any foreign particles within each vial and when withdrawn into the syringe. **Do not use if there are any foreign particles.**
4. If foreign particles are observed, promptly contact Genzyme Medical Information at 800-745-4447 (option 2). Genzyme will provide replacement product and will

work with you regarding options for re-scheduling or proceeding with the Thyrogen treatment/testing protocol.

5. Please return vials containing foreign particles per instructions to be provided by Genzyme Medical Information.

As stated in the approved product labeling, thyroid hormone withdrawal remains the standard diagnostic modality and therefore is an alternative to Thyrogen, should concern remain.

Should you require further information or have any questions, please do not hesitate to contact Genzyme Medical Information at 800-745-4447 (option 2) or by email at medinfo@genzyme.com.

Yours sincerely,

A handwritten signature in black ink, appearing to read "W. Blair Okita". The signature is fluid and cursive, with the first name "W. Blair" and the last name "Okita" clearly distinguishable.

W. Blair Okita, PhD
Senior Vice President
Quality and Technical Operations

