



1 DNA Way  
South San Francisco  
CA 94080-4990  
650-225-1000

August 3, 2001

## **IMPORTANT COUNTERFEIT DRUG WARNING**

*COUNTERFEITING OF NUTROPIN AQ®*

Dear Growth Hormone patient:

Genentech, Inc. has become aware of the existence of counterfeit Nutropin AQ® [somatotropin (rDNA origin) injection] in the U.S. Genentech is voluntarily issuing an important drug warning regarding the existence of counterfeit drug falsely labeled as Nutropin AQ®. Safety of our patients is of utmost importance and we are cooperating fully with the U.S. Food and Drug Administration (FDA) to investigate this matter and prevent further distribution of counterfeit product.

To our knowledge, the counterfeit product has been found in several states. We are certain that it was neither manufactured nor distributed by Genentech. Although the original source of the counterfeit product is unknown, it is our understanding that Mediq/ACS distributed the counterfeit product reported to Genentech. As Mediq/ACS does not have a purchase or distribution agreement with Genentech for Nutropin AQ® or for any other product manufactured or marketed by Genentech, we can be certain that they did not purchase their Nutropin AQ® from Genentech. We have been notified of four pharmacies from which patients did in fact receive counterfeit product: Pediatric Services of America, Curascript Pharmacy, Bay Area IV Therapy and Memorial Home Care.

Genentech has a tracking system in place that monitors the distribution of Nutropin AQ® through approved distributors that purchase directly from the company. Because of this, we were able to quickly identify the source of the counterfeit product as being from a non-approved distributor. If you are in possession of Nutropin AQ® dispensed to you through a source that purchased the product directly from Genentech, we believe it is not counterfeit. If you have any concerns regarding your Nutropin AQ®, please verify with your pharmacy that they did indeed purchase directly from Genentech or from a wholesaler who purchased directly from Genentech.

We have notified all current Genentech human growth hormone distributors and dispensing pharmacies of record of this issue and have reiterated the importance of purchasing Genentech products directly from Genentech or from one of our authorized distributors. Purchasing Nutropin AQ® from the proper channels will help to ensure that you, as a patient, receive products that are in conformance with U.S. and international Good Manufacturing Practice (GMP) compliance standards.

Adverse events reported thus far with the counterfeit Nutropin AQ® are swelling, itching or painful burning at the injection site. The FDA forensic laboratory has determined that seven vials of counterfeited product tested from lot L9101A4 and one counterfeit vial of lot L9043A1 were found to contain human insulin. Sample vials of counterfeit product from the remaining two lots, L9504A2 and L9504A3, did not contain any active ingredient.

FDA also stated that these are counterfeit products produced by unknown persons in unknown locations and under unknown manufacturing conditions and controls. Although two lots appear to be produced with one formulation while the other two have a different formulation, there is no certainty that the samples the FDA has analyzed represent all product packaged under those lot numbers and contents may vary.

To date, all product identified as counterfeit has been submitted to the FDA, which is coordinating testing of the vial contents. If you suspect that you are in possession of any counterfeit product, please contact your physician or dispensing pharmacy or contact the FDA Drug Information Branch, Center for Drugs, at (301) 827-4570.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan D. Hellman". The signature is fluid and cursive, with a large loop at the end.

Susan D. Hellman, MD, MPH  
Executive Vice President  
Chief Medical Officer  
Genentech, Inc.