

# Genzyme CEO With "Zero Tolerance for Screwups" Has a 14-Year History of Them

By Jim Edwards | Mar 24, 2010

It's not a surprise that [Genzyme \(GENZ\) must now reach a consent decree with the FDA](#) over manufacturing standards at its Allston, Mass., plant. Genzyme's troubles at the plant — including trash found floating in some of the genetic therapies it makes — are well-known.

What is less well-known is how pervasive these problems are: Genzyme, which specializes in drugs for unusual genetic diseases, has basically been failing FDA inspections on and off since 1996. Currently, [42 percent of its entire product sales revenue stream](#) is under FDA observation, and the feds have prevented it from making new drugs.

CEO **Henri Termeer**, however, has had 14 years to get his act together, according to [an archive of FDA warning letters](#). Here's the timeline, but before you read it bear in mind this [quote from Termeer about his love of ballet](#), given to Boston magazine:

"I'm drawn to the complete zero tolerance for screwups," he says in an accent that turns th's to d's and s's to z's. "Failure is so visible and the tolerance for anything that doesn't quite work isn't there. I like perfection and courage and innovation."

**1996:** FDA cites Genzyme for not properly monitoring its research studies.

**1998:** [FDA cites Genzyme again](#) for the same reason (this letter mentions the 1996 warning).

**2001:** Genzyme fails its first [manufacturing inspection for Synvisc](#), an arthritis injection treatment.

**2007:** Genzyme fails a [Thymoglobulin manufacturing inspection](#).

**2008:** Genzyme fails manufacturing [inspection of its various genetic disease therapies](#). This series of FDA inspections would eventually encompass **Cerezyme, Fabrazyme, Myozyme, Thyrogen, Aldurazyme** and **Thymoglobulin**.

**February 2009:** Another manufacturing [warning letter](#).

**November 2009:** [FDA prevents Genzyme from making Lumizyme](#), another genetic therapy.

**Also that month:** the FDA requires Genzyme to send a "[dear doctor](#)" letter warning physicians of bits of rubber and metal in Genzyme's drugs.

**Yesterday afternoon:** [FDA requires Genzyme to come to a consent decree](#) regarding its manufacturing.

Termeer also told Boston mag, "I like, well, I like being judged." He must be in heaven.

*Jim Edwards, a former managing editor of Adweek, has covered drug marketing at Brandweek for four years, and is a former Knight-Bagehot fellow at Columbia University's business and journalism schools.*