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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: Docket No. 2006N-0181 Product Stability Data; Notice of Pilot Project, Request to Participate

11 July 2006

Dear Sir/Madam:

With this letter, Genzyme submits request to participate in a pilot project involving the testing of a Health Level 7 (HL7) data interchange standard for the submission of product stability data to FDA to facilitate the review of this data. Using the data interchange standards and the analytical tools will allow consistent data presentation to the agency and allow a reviewer to more efficiently and consistently display and evaluate product stability data submitted in electronic format.

Genzyme has been actively involved in other HL7 initiatives at the FDA such as Structured Product Labeling (SPL) and emerging standards such as Regulated Product Submissions (RPS). Over the past few months, we worked closely with the FDA in the testing of its Electronic Submissions Gateway (ESG) project.

Genzyme looks forward to the opportunity to participate in this pilot program. Please contact me at 617-768-6652 or Linda Temple at 617-768-9290 should you have any questions regarding this letter.

Cordially,

Monica P. Mehta
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LET 2