



sanofi aventis

Because health matters

August 29, 2005

Via fax and UPS

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

Re: Docket No. 2005N-0262

Notice of Pilot Program on the Submission of Chemistry, Manufacturing, and Controls Information in a New Drug Application Under the New Pharmaceutical Quality Assessment System

Dear Sir/Madam:

In reference to the above *Notice of Pilot Program on the Submission of Chemistry, Manufacturing, and Controls Information in a New Drug Application Under the New Pharmaceutical Quality Assessment System*, Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, member of the sanofi-aventis Group, acknowledge the FDA's commitment in moving forward with the New Pharmaceutical Quality Assessment System. However, sanofi-aventis will not participate in the proposed FDA Pilot Program at this time.

Sincerely,

Steve Caffé, M.D.
Vice President, US Deputy Head
Regulatory Development

2005N-0262

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