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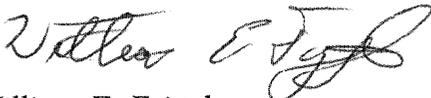
January 18, 2002

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

RE: Response to Docket No. 01N-0496, Patient Profile Viewer;
Notice of Pilot Project

As a follow-up to the enclosed e-mail, and in response to Docket No. 01N-0496, Patient Profile Viewer; Notice of Pilot Project, Sanofi-Synthelabo would like to confirm our interest in participating in the FDA Patient Profiles Pilot Project. I am the contact person for this effort at Sanofi-Synthelabo, and I can be reached at (610) 889-8648.

Sincerely,



William E. Friggle
Associate Director
Scientific Information Systems

WEF:lmb

Enclosure (1)

01N-0496

APE 9

Sanofi-Synthelabo Research

A division of Sanofi-Synthelabo Inc.

9 Great Valley Parkway, Malvern, PA 19355 - Tel.: (610) 889-8600

William Friggle

12/31/2001 08:22 AM

To: levinr@cder.fda.gov

CC:

Subject: Patient Profile

Randy,

I believe that we are very interested in participating in the Patient Profiles Pilot effort recently announced in the Federal Register. As I am confirming the green light from our senior management, I would like to know if you can give me any further idea about 1) Exactly what the commitment is; 2) When the effort will start; and 3) How long it will last? We have made numerous submissions of electronic Item 11 and have a reasonable familiarity with the CDISC data standards. I hope to be able to contact you very shortly with the final confirmation of our intention to participate.

One other question. When you and I last spoke in Philadelphia at the DIA Workshop about the tools the FDA uses, you mentioned that you could possibly give us feedback on our Item 11 Define files. We would be very interested in this since we are in the process of trying to make decisions about how to proceed with our internal processing. Can you possibly give us feedback on the submissions that we have made (please see NDA 21-345 [recently approved], NDA 21-287 [still under review], and sNDA 20-839 [still under review])? I am particularly interested in your comments about our Item 11/Define file layout, organization, etc.

Thanks in advance for your feedback on both of these issues.

Bill Friggle
Sanofi-Synthelabo
610 889-8648

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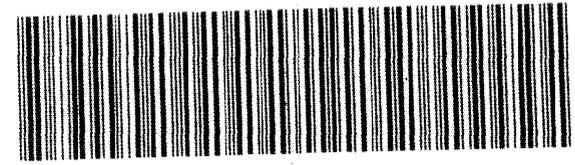
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