



Philip Bentley, Ph.D.  
Vice President, Preclinical Safety, U.S.  
One Health Plaza  
East Hanover, NJ 07936  
Phone: (862) 778-2062  
Fax: (973) 781-3757  
Email: [philip.bentley@pharma.novartis.com](mailto:philip.bentley@pharma.novartis.com)

4-February-2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Docket No. 02N-0532 Nonclinical Datasets; Notice of Pilot Project

Gentlemen:

Novartis Pharmaceuticals would be very interested to participate in the pilot project and assist the FDA in testing the use of various analysis tools for standard nonclinical data and metadata. Novartis is currently participating in the initiative to develop standards for nonclinical datasets, similar to CDISC, so we are very familiar with work that has occurred and is ongoing. We will make internal resources available to participate in this pilot project and look forward to working with you.

Sincerely Yours,

A handwritten signature in black ink, appearing to read 'P. Bentley', written in a cursive style.

Philip Bentley, Ph.D.  
Vice President, Preclinical Safety, U.S.

02N-0532

LET 1