

Pharmaceutical
Division

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Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone: 203 812-2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MC 20852

Docket No. 01N-0496

December 20, 2001

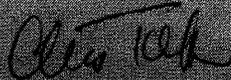
To whom it may concern:

This letter is to request participation by Christine Tolk, Bayer Corporation, Global Biometry to participate in the Patient Profiler Pilot Project, Docket No. 01N-0496.

I have been a member of the SDS group of CDISC for the past two years. Bayer is willing to provide my time to work with the agency to test the patient profile viewer (PPV) with standard data sets. The data set that Bayer would provide will contain live data where the treatment groups have been artificially modified.

I look forward to hearing from you in the near future.

Sincerely,



Christine Tolk

Global Medical Standards Manager
Phone: 203-812-2067
Email: christine.tolk.b@bayer.com

cc: Holly Coulter (Bayer)
Randy Levin (FDA)

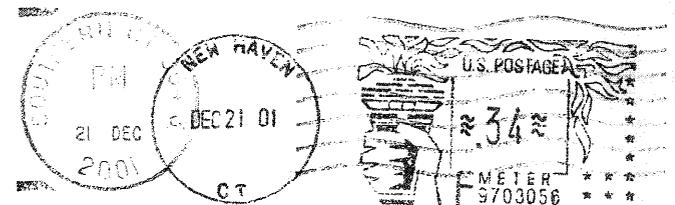
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