

Procter & Gamble

The Procter & Gamble Company
Miami Valley Laboratories
P.O. Box 538707, Cincinnati, Ohio 45253-8707

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Pharmaceuticals

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852
<http://www.fda.gov/dockets/ecomments>
levinr@cdcr.fda.gov

RE: Request to participate in pilot project
Docket No. 02N-0532
General Correspondence

Dear Mr. Levin,

I am writing to request our involvement in the pilot project on electronic submission of Nonclinical Datasets (Docket No. 02N-0532). Procter & Gamble Pharmaceuticals would like to participate and contribute to this project. Please note that Procter & Gamble Pharmaceuticals has been involved in the ongoing clinical dataset project through the leadership of Dr. Fred Wood, Clinical Data Management. We are currently re-applying that experience to the management of nonclinical data. In addition, we have submitted electronic datasets for tumor studies on two different programs, risedronate¹ and azimilide² in accordance with guidance provided by the agency at the time of filing.

Please communicate directly with me, Dr. David Eastman, Ph.D. at the address below concerning this project.

Nonclinical Data Management,
Drug Safety Assessment
Procter & Gamble Pharmaceuticals
Miami Valley Laboratories
11810 E. Miami River Road
Cincinnati, OH 45252
513/627-0688 phone
513/627-0929 Fax
eastman.df@pg.com

Sincerely,



David F. Eastman, Ph.D.
Senior Toxicologist,

1 NDA #20-835, Supplements 001,002, and 003, 4 January 1999

2 NDA #21-054 Serial #173 16 April 1998 and Serial #198, 29 September 1998

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