Procter&Gamble

The Procter & Gamble Company Health Care Research Center 8700 Mason-Montgomery Road, Mason, Ohio 45040-9462 1533 '02 FEB 12 P2:23

February 5, 2001

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

Re: Docket No. 00N-1669; Electronic Filing of Drug Registration and Listing Information: Notice of Pilot Project

Dear Sir or Madam:

The Procter & Gamble Company (P&G) herewith submits a request to participate in the pilot project involving the electronic filing of drug registration and listing information, as presented in the Federal Register, Vol. 66, No. 6, January 9, 2001 pp 1684-1685. We are willing to test specific aspects of the electronic filing system, as you request, and to provide technical feedback. We understand that existing registration and listings requirements will not be waived, suspended, or modified and that we must continue to submit paper documents in accordance with FDA's existing filing requirements.

Based on a phone conversation I had with Mr. James Hunter on January 29th, it is our understanding it is not essential that we list all of our products or register all of our plants in this pilot project. Therefore, we propose to drug list approximately 100 Over-the-Counter drugs, which we both manufacture and distribute and currently have listed, recognizing not all of these will have changes that would require listing during any six month period. We also propose to electronically register at least four of P&G's manufacturing plants currently registered with the agency.

The participant will be me, Ms. Nancy Allen, located at the following address: The Procter & Gamble Company Health Care Research Center, Box 589 8700 Mason-Montgomery Road Mason, OH 45040-9462

I can be reached by phone at 513-622-2465 or by FAX at 513-622-0521. Electronic mail address is Allen.NH@PG.com. If you have questions concerning this request to test the pilot system, please contact me.

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Sincerely,

Nancy H. Allen Regulatory Affairs

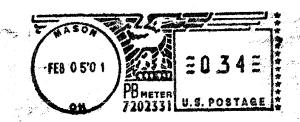
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Hancy H. allen

Copy: James R. Hunter

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