Boehringer Ingelheim

Boehringer Ingelheim
Pharmaceuticals, Inc.

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

January 10, 2001

Marilyn Z. Maxwell
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900 Ridgebury Rd/P.O. Box 368
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Telephone (203) 798-9988

Re: Docket No. 00N-1669
Electronic Filing of Drug Registration and Listing Information
66 FR 1684, Published January 09, 2001

Dear Madam or Sir:

In response to the above-referenced FEDERAL REGISTER Notice and on behalf of Boehringer Ingelheim Pharmaceuticals, Inc., I would like to volunteer to participate in the pilot project involving the electronic filing of drug registration and listing information.

The following is provided for your consideration:

Participants Name:	Marilyn Maxwell, Manager Drug Regulatory Affairs
Company Name and Address:	Boehringer Ingelheim Pharmaceuticals, Inc 900 Ridgebury Road, P.O. Box 368 Ridgefield, CT 06877-0368
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00N-1669

Lab 1

Under Labeler Code 000597, there are about 40 human prescription products currently listed with the agency. There is one establishment registered (Registration No. 1219767) with two firms doing business at this site. The processes currently performed by Boehringer Ingelheim Pharmaceuticals, Inc. are manufacture of aerosol prescription drug products and distribution of human prescription drug products.

In addition, I am the U.S. Agent for the drug listing responsibilities on behalf of four Boehringer Ingelheim foreign companies including our parent company manufacturing facility Boehringer Ingelheim Pharma. KG, under Labeler Code 012714. Both drug substances and human prescription drug products are manufactured by these foreign firms and exported to the U.S.

I am looking forward to participating in this pilot project and would like to take this opportunity to thank you for your kind consideration in this matter.

Sincerely,

Marilyn Z. Maxwell, Manager
Drug Regulatory Affairs