

Bristol-Myers Squibb Pharmaceutical Research Institute

P.O. Box 4000 Princeton, NJ 08543-4000 609 252-4000

Docket No. 00N-1669

6577 '01 JAN 23 P2:36

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

January 15, 2001

Dear Sir/Madam:

The Pharmaceutical Research Institute (PRI) of the Bristol-Myers Squibb Company wishes to be considered for participation in the FDA's pilot program for the electronic submission of files to satisfy the requirements of 21CFR Part 207. The participants are:

Howard M. Kessler (609-252-4536)
Amy N. Grant (609-252-4786)
Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543

The PRI is currently responsible for the drug listing of finished, human, prescription and OTC drug products under many labeler codes. The labeler codes and associated information are presented below:

United States/Puerto Rico Establishments

- 0003 – E.R. Squibb & Sons: ~150 products listed for manufacturer, distributor, or both
- 0015 – Mead Johnson & Company: ~95 products listed for manufacturer, distributor, or both
- 0087 – Bristol-Myers Squibb Company: ~90 products listed for manufacturer, distributor, or both
- 12783 – Bristol-Myers Squibb Manufacturing: ~25 products listed for manufacturer
- 15548 – Bristol-Myers Squibb Laboratories: ~50 products listed for manufacturer
- 51305 – Bristol-Myers Squibb Caribbean: ~25 products listed for manufacturer
- 55961 – Bristol-Myers Barceloneta: ~55 products listed for manufacturer

Ex-US Establishments

- 12698 – Bristol-Myers Squibb S.p.A.-Anagni (Italy): ~2 products listed for manufacturer
- 17101 – Bristol-Myers Squibb S.p.A. (Italy): ~10 products listed for manufacturer
- 64747 – Bristol-Myers Squibb Australia: ~2 products listed for manufacturer

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A Bristol-Myers Squibb Company

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Each of the above labeler codes has at least one registered establishment associated with that code.

We look forward to working with you on the development of this important, new system.

Sincerely,



Howard M. Kessler
Associate Director
Dossier Planning and Management
Regulatory Science

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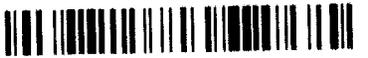
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Pharmaceutical Research Institute

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