36 PERRIGO

February 6, 2001

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

-7 A9

Re:

Docket No. 00N - 1669

Electronic Filing of Drug Registration and Listing

Information:

Notice of Pilot Project

Participant: Ms. Carrie Phillips

L. Perrigo Company (Labeler code 000113)

515 Eastern Avenue Allegan, MI 49010 Phone - (616)673-9228

Dear Sir or Madam:

The L. Perrigo Company (Perrigo) respectfully requests to participate in the Electronic Filing of Drug Registration and Listing Information Pilot Project.

Perrigo is the nation's largest private-label manufacturer of OTC drug products, serving numerous mass merchandisers, chain drugstores and supermarkets. Most of the OTC products are marketed under existing OTC monographs. A small, but growing, volume of Perrigo's OTC products is covered by approved abbreviated new drug applications (ANDAs).

Perrigo would appreciate the opportunity to participate and provide feedback on the FDA's Electronic Filing process. Perrigo believes its participation in the Pilot Project would be beneficial to both Perrigo and the Agency due to the volume of reporting and vast experience with the drug listing process.

- The primary function of Perrigo is manufacturing OTC products, but in addition Perrigo distributes those products under several Perrigo label names. Perrigo also acts as a relabeler, and a repacker.
- Over 200 over-the-counter (OTC) human drug products are actively listed with the FDA.
- Four manufacturing sites are registered.

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Please feel free to contact Carrie Phillips at (616) 673-9228 if there are any questions or if Perrigo may be of further assistance.

Singerely,

Heidi Horn

Regulatory Affairs Manager

Perrigo Company

From: Denise Kosiara (616)673-9276 Perrigo Company 502 Eastern Avenue Plant 6

Allegan, MI, 49010

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