PERRIGO®

December 28, 2000

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

2548 '00 DEC 29 A9:40

Re: Docket No. 00N - 1567
Agency Information Collection Activities;
Proposed Collection; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

Dear Sir or Madam:

The L. Perrigo Company (Perrigo) submits these comments in response to the Food and Drug Administration's (FDA) solicitation for comments on the requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

Introduction

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 shares the FDA's commitment to the health and safety of consumers and is aware of situations where FDA has had the need to contact manufacturers and distributors of certain products. In these instances, FDA used previous drug listings to facilitate this communication in a timely manner. Based on this utility of the information, Perrigo is in agreement with the continued registration of producers and the listing of drugs in commercial distribution.

Drug Listing at Perrigo

Historically Perrigo has submitted an average of 131 Form 2657's for the products it manufacturers at each drug listing submission. Perrigo also elects to fulfill the listing requirements for 108 private label customers. This results in an average of 422 listings on Form 2658 at each biannual submission. Perrigo estimates the total hours spent completing a drug listing submission at 320 hours.

Recently, at the request of the FDA, Perrigo implemented a quarterly drug listing schedule versus the biannual schedule required by 21 CFR 207.30. The basis of this request was to ease FDA's burden of processing the large volume of information submitted by Perrigo.

00N-1567

C2

515 Eastern Avenue
Allegan, Michigan 49010
(616) 673-8451

PERRIGO®

Perrigo Suggestions for Amending the Collection of Drug Listing Information

Perrigo agrees with the necessity for providing the Agency with the information currently required on Forms 2657 and 2658. However, Perrigo feels that the burden of drug listing could be greatly reduced if the FDA were to eliminate the requirement to send a representative label and/or carton with each Form 2657 and 2658 submitted. Representative labeling would be available and supplied to FDA upon request.

Perrigo estimates that the time required to prepare a drug listing submission without representative labeling would be reduced by 75% (240 hours). The processing time and the volume of information requiring storage by FDA would also be significantly reduced.

In addition, by preventing the time-consuming and tedious task of matching mailed labels and cartons to the 2657s and 2658s, it would facilitate the feasibility of electronic submissions, further reducing the amount of information to be transferred and stored.

Conclusion

Through the close working relationship Perrigo has developed with the drug listing branch of the FDA, Perrigo understands the extreme burden of the current process. Therefore, it is requested that the FDA consider Perrigo's recommendation to simplify the gathering, processing and storage of information by eliminating the requirement to submit representative labels and/or cartons.

Perrigo appreciates the opportunity to provide comments on FDA's drug listing process. Please feel free to contact Carrie Phillips at (616) 673-9228 or myself at (616) 673-7612 if there are any questions or if Perrigo may be of further assistance.

Sincerely,

Heidi Horn

Heidi Horn
Regulatory Affairs Manager
Perrigo Company

515 Eastern Avenue
Allegan, Michigan 49010
(616) 673-8451

From: Carrie Phillips (616)673-9228
Perrigo Company
502 Eastern Avenue
Plant 6
Allegan, MI, 49010

SHIPPER'S FEDEX ACCOUNT #

FedEx.

To: Dockets Management Branch (HFA-305) (301)827-1482
Food & Drug Administration
5630 Fishers Lane, Room 1061

Rockville, MD, 20852

SHIP DATE: 28DEC00
WEIGHT: 1 LBS

Ref: 10307180

DELIVERY ADDRESS
TRK # 7919 3257 2875 FORM 0201

PRIORITY OVERNIGHT

FRI
AA
Deliver by:
29DEC00

IAD

20852-MD-US

NH GAIA