PERRIGO®

September 19, 2001

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

8018 '01 SEP 24 A9:19

Subject:

AMENDMENT TO APPLICATIONS FOR EXEMPTION
Docket No. 98N-0337

Cimetidine Tablets, 200 mg
ANDA 75-285
APP18

Clemastine Fumarate Tablets USP, 1.34 mg
ANDA 74-512
APP19

Doxylamine Succinate Tablets, 25 mg
ANDA 40-167
APP 20

Loperamide Hydrochloride Tablets, 2 mg
ANDA 75-232
APP21

Loperamide Hydrochloride Oral Solution 1 mg/5mL
ANDA 73-243
APP22

Pseudoephedrine Hydrochloride Tablets 120 mg, Extended Release
ANDA 75-153
APP23

Loperamide Hydrochloride Tablets, 2 mg
ANDA 74-194
APP24

Miconazole Nitrate Vaginal Cream 2%
Miconazole Nitrate Suppositories, 200 mg
(Combination Pack)
ANDA 75-329
APP25

98N-0337

AMD2

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

Minoxidil Topical Solution USP, 2%
ANDA 75-357
APP26

Minoxidil Topical Solution USP, 5% (For Men)
ANDA 75-598
APP27

Statement of Purpose

On July 20, 2001, Perrigo filed petitions regarding each of the above listed ANDAs. Pursuant to 21 CFR 201.66(e), these petitions requested exemptions in the form of temporary deferrals of the implementation of the requirements under 21 CFR 201.66(c) and (d). The deferrals were requested because there is not currently approved labeling in the Drug Facts format for the reference listed drugs available to the Perrigo Company.

Clarification to Perrigo of the FDA Position

On September 12, 2001, in a telephone conversation between Mr. Gerald Rachanow in the Division of OTC Drugs and Brian Schuster, Regulatory Affairs Manager of the Perrigo Company, certain aspects of the FDA implementation of the regulation were clarified. Following is a summary of that discussion:

Mr. Rachanow stated that there had been consultation with Dr.Charles Ganley, Director of the Office of OTC Drug Products, and John Grace in the Office of Generic Drugs. The Office of Generic Drugs will now approve Changes Being Effected supplemental ANDA applications for a change in format to Drug Facts Labeling (DFL) based on the OGD issued labeling templates even in the absence of approved Reference Listed Drug labeling in DFL format. Labeling templates currently posted on the FDA website will not be revised and will be the basis for approval of DFL for ANDA OTC products, with one exception, as noted below.

The 10 Perrigo petitions may be divided into three categories:

Category 1
Products for which a final template is available on the FDA website. Approval of DFL will be granted by means of a CBE supplement:

Cimetidine Tablets, 200 mg
ANDA 75-285
APP18

Loperamide Hydrochloride Tablets, 2 mg
ANDA 75-232
APP21

Loperamide Hydrochloride Oral Solution 1 mg/5mL
ANDA 73-243
APP22

Loperamide Hydrochloride Tablets, 2 mg
ANDA 74-194
APP24

Miconazole Nitrate Vaginal Cream 2%
Miconazole Nitrate Suppositories, 200 mg
(Combination Pack)
ANDA 75-329
APP25

Category 2
Products for which a template is posted, but will be changed soon.

Minoxidil Topical Solution USP, 2% (for men and for women)
ANDA 75-357
APP26

Category 3
Products for which a template is not now posted but will be at some time in the future (perhaps by October).

Clemastine Fumarate Tablets USP, 1.34 mg
ANDA 74-512
APP19

Doxylamine Succinate Tablets, 25 mg
ANDA 40-167
APP 20

Pseudoephedrine Hydrochloride Tablets 120 mg,
Extended Release
ANDA 75-153
APP23

Minoxidil Topical Solution USP, 5% (For Men)
ANDA 75-598
APP27

Note: For Minoxidil 5%, a template is not now posted but will be posted at the same time that the template for Minoxidil 2% is modified.

Mr. Rachanow indicated that if there is any apparent inconsistency between the regulations and the FDA template, applicants should use the FDA template.

In consideration of this information, Perrigo hereby amends the petitions filed on July 20, 2001, as follows:

Request for Withdrawal of Certain Petitions

Perrigo Company hereby requests the withdrawal of the petitions as listed under "Category 1" above. Appropriate supplements will be filed for these applications based on the current final FDA templates to ensure that labeling conforms to the DFL format by the May 2002 compliance date.

Amendment of Additional Information to Certain Petitions

Perrigo Company hereby amends the petitions as listed under "Category 2" and "Category 3" above, as follows.

Due to the large number of store-brand private labels maintained by Perrigo for each ANDA OTC drug product, converting the labeling to Drug Facts format requires significant time and resources. For those products for which neither approved reference listed drug labeling in Drug Facts format nor a final FDA template is available as of the date of this letter, Perrigo requests a temporary deferral of implementation of the requirements under 21 CFR 201.66(c) and (d).

Perrigo will make every effort to conform to the May 2002 compliance date. At the time that approved reference listed drug labeling in DFL format or a final FDA template becomes available for each product, Perrigo will immediately act to file a Changes Being Effected Supplement for approval of the new labeling in the relevant ANDA. The product will then be entered into our labeling conversion schedule.

Due to the length of time required to prepare labeling, submit a CBE supplement, and finally convert the labeling of a product, we anticipate that conversion for a particular product can be accomplished within approximately six months from the filing of the supplement, assuming that there are no changes required following OGD review. We anticipate that changes may only be required if the submitted labeling is based on RLD labeling that did not receive FDA review or approval prior to marketing. An ANDA applicant may not be able to accurately determine whether an OTC reference listed drug product purchased at retail contains labeling that has been approved by FDA prior to being marketed.

For example, Perrigo filed a Changes Being Effected supplement to Clemastine Fumarate Tablets USP, 1.34 mg, ANDA 74-512 (APP19) on August 30, 2001, to convert to DFL format based on the reference listed drug labeling now being marketed in DFL format. We have been unable to determine whether this labeling is approved and so must continue to request a deferral for that ANDA until either the supplement is accepted by OGD or a final DFL template is published.

Length of the Deferral Requested

For each of the products listed in Category 2 and Category 3, above, we request the following schedule of deferrals based upon the date of availability of the final DFL template or approved RLD labeling:

Final DFL Template Issued for the Product	**Deferral Requested**
Before 10/01/2001	No deferral requested
10/01/2001 to 10/31/2001	Deferral of 30 days
11/01/2001 to 11/30/2001	Deferral of 60 days
12/01/2001 to 12/31/2001	Deferral of 90 days
01/01/2002 to 01/31/2002	Deferral of 120 days
02/01/2002 to 02/28/2002	Deferral of 150 days
03/01/2002 to 03/31/2002	Deferral of 180 days
04/01/2002 to 04/30/2002	Deferral of 210 days
05/01/2002 to 05/31/2002	Deferral of 240 days

This schedule of requested deferrals is necessary because of the uncertain timing of the issuance of the final DFL templates and the certain compliance date of May 2002.

If there are any questions concerning this request, please contact me by phone at (616) 673-9745 or fax at (616) 673-7655. Thank you for your attention to this matter.

Sincerely,

L. PERRIGO COMPANY

Brian Schuster
Manager, ANDA Submissions

CC:
Gary Buehler, Director
Office of Generic Drugs

Gerald Rachanow
Regulatory Counsel, Division of OTC Drug Products

John Grace
OGD Labeling Review Branch

From: Brian Schuster (616)673-9745
Perrigo Company
502 Eastern Avenue
Plant 6
Allegan, MI, 49010

REVENUE BARCODE

FedEx.

To: Dockets Management Branch (HFA 305) (301)594-1086
Food & Drug Administration
5630 Fishers Lane Room 1061
DOCKET NO. 98N-0337
Rockville,, MD, 20852

SHIP DATE: 21SEP01
WEIGHT: 1 LBS

Ref: Amend to Appl for Exempt

DELIVERY ADDRESS BARCODE(FEDEX-EDR)

FedEx PRIORITY OVERNIGHT

MON
AA
Deliver by:
24SEP01

TRK # 7901 6460 8947 FORM 0201

IAD

20852-MD-US

NZ GAIA