DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

L. Perrigo Company
Attention: Brian Schuster
Manager, ANDA Submissions
515 Eastern Avenue
Allegan, Michigan 49010

DEC 14 2001

RE: Docket No. 98N-0337
Applications for Exemption
APP 18 through APP 27

Dear Mr. Schuster:

We are responding to your applications for exemption, dated July 20, 2001, for a temporary deferral of the implementation of the requirements of 21 CFR 201.66(c) and (d) for the following over-the-counter (OTC) drug products:

Application No.	ANDA No.	Product
APP18	75-285	Cimetidine Tablets 200 mg.
APP19	74-512	Clemastine Fumarate Tablets 1.34 mg.
APP20	40-167	Doxylamine Succinate Tablets 25 mg.
APP21	74-194	Loperamide Hydrochloride Tablets 2 mg.
APP22	73-243	Loperamide Hydrochloride Oral Solution 1 mg.
APP23	75-153	Pseudoephedrine HCl 120 mg. Extended Release
APP24	75-232	Loperamide Hydrochloride Tablets 2 mg.
APP25	75-329	Miconazole Nitrate Vaginal Cream 2%/Miconazole Nitrate Suppositories 200 mg. Combination Pack
APP26	75-357	Minoxidil Topical Solution 2%
APP27	75-598	Minoxidil Topical Solution 5% for Men

You stated a number of reasons to support your request, which we are not restating here.

On September 19, 2001, you amended your applications for exemption in follow-up to a telephone conversation with Mr. Gerald Rachanow of our division on September 12, 2001. In your amendment, you requested withdrawal of applications 18, 21, 22, 24, and 25 because the labeling templates for these products currently posted on the FDA website will not be revised and can be used as the basis for agency approval of Drug Facts labeling for these products. The agency considers these five applications for exemption as withdrawn.

98N-0337 LET 11

Mr. Rachanow had informed you that the labeling template for minoxidil topical solution 2% (for men and for women), which is posted on the website, will be changed soon, and that the agency planned in the future to post on the website additional labeling templates for the products covered by the other four applications for exemption. Based on that information, you amended your applications for exemption to request a deferral of the following time periods based upon the date of availability of the final agency Drug Facts labeling template or approved reference listed drug (RLD) labeling in Drug Facts format:

Labeling Availability Date	Deferral Requested
Before 10/01/2001	No deferral requested
10/01/2001 to 10/31/2001	30 days
11/01/2001 to 11/30/2001	60 days
12/01/2001 to 12/31/2001	90 days
1/01/2002 to 1/31/2002	120 days
2/01/2002 to 2/28/2002	150 days
3/01/2002 to 3/31/2002	180 days
4/01/2002 to 4/30/2002	210 days
5/01/2002 to 5/31/2002	240 days

You stated that at the time that approved RLD labeling in Drug Facts format or a final FDA template becomes available for each product, your company will immediately file a Changes Being Effected (CBE) Supplement for approval of the new labeling in the relevant ANDA and the product will then be entered into your labeling conversion schedule. You added that due to the length of time required to prepare labeling, submit a CBE Supplement, and finally convert the product labeling, you anticipate that conversion for a particular product can be accomplished approximately 6 months from the filing of the supplement, assuming no changes are required following agency review of the Supplement.

Based on the time that it has taken to finalize current FDA Drug Facts template labeling for ANDA drug products and the anticipated availability of the additional template labeling, as noted above, we consider your timetable for concurrent implementation of labeling revisions for a number of OTC drug products to be appropriate. Accordingly, we are granting deferrals, as a matter of enforcement discretion, for APP 19, 20, 23, 26, and 27 in accord with your requested deferral schedule. These deferral times would be the number of additional days that would be allowed after May 16, 2002, to comply with the new Drug Facts labeling requirements. For APP26 (Minoxidil Topical Solution 2%), the number of days would be determined based upon the date of availability of the revised agency Drug Facts labeling template. For APP19, 20, 23, and 27, the number of days would be determined based upon the date of availability of the new Drug Facts labeling templates that the agency is developing or the date of approved reference listed drug (RLD) labeling in Drug Facts format, whichever occurs first.

If you have any comments or questions regarding these deferrals, please reference the docket and application for exemption numbers and submit them to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. I hope this information is helpful.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research