

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-618**

**21-681**

**21-682**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-618  
NDA 21-681  
NDA 21-682

Presutti Laboratories, Inc.  
Attention: John Presutti  
President  
1607 N. Douglas Avenue  
Arlington Heights, IL 60004

Dear Mr. Presutti:

Please refer to your new drug applications (NDAs) dated July 16, 2003, received July 17, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Tindamax™ (tinidazole tablets), 250 and 500 mg.

We acknowledge receipt of your submissions dated:

September 15, 2003	March 23, 2004	May 12, 2004
September 29, 2003	April 7, 2004	May 13, 2004
January 16, 2004	April 12, 2004	May 14, 2004
January 19, 2004	May 6, 2004	May 17, 2004

These new drug applications provide for the use of Tindamax™ (tinidazole tablets) for the treatment of trichomoniasis (NDA 21-618), the treatment of giardiasis (NDA 21-681), and the treatment of amebiasis and amebic liver abscess (NDA 21-682).

We completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted on May 14, 2004) and the immediate container and carton labels submitted on May 12, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions “**FPL for approved NDAs 21-618, 21-681, and 21-682.**” Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

- We note that you have fulfilled the pediatric study requirement for the treatment of trichomoniasis caused by *T. vaginalis* in post-menarchal female patients and post-pubertal male patients (NDA 21-618). We are waiving the pediatric study requirement for the treatment of trichomoniasis caused by *T. vaginalis* in pre-menarchal female patients and pre-pubertal male patients.
- We note that you have fulfilled the pediatric study requirement for the treatment of giardiasis caused by *G. duodenalis* (also termed *G. lamblia*) in pediatric patients over 3 years of age (NDA 21-681). We are deferring submission of your pediatric studies for the treatment of giardiasis caused by *G. duodenalis* (also termed *G. lamblia*) for ages 0 months to 3 years until May 1, 2009.
- We note that you have fulfilled the pediatric study requirement for the treatment of intestinal amebiasis and amebic liver abscess caused by *E. histolytica* in pediatric patients over 3 years of age (NDA 21-682). We are deferring submission of your pediatric studies for the treatment of intestinal amebiasis and amebic liver abscess caused by *E. histolytica* for ages 0 months to 3 years until May 1, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the treatment of giardiasis caused by *G. duodenalis* (also termed *G. lamblia*) in pediatric patients ages 0 months to 3 years.

Final Report Submission: May 1, 2009.

2. Deferred pediatric study under PREA for the treatment of intestinal amebiasis and amebic liver abscess caused by *E. histolytica* in pediatric patients ages 0 months to 3 years.

Final Report Submission: May 1, 2009.

Submit final study reports to NDA 21-618. For administrative purposes, all submissions related to these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments.**"

We remind you of your postmarketing study commitment in your submission dated May 17, 2004. This commitment is listed below.

A 30-day toxicity study in dogs in order to comply with ICH Guidance (M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals).

Protocol Submission: Within 4 months of the date of this letter  
Study Start: Within 8 months of the date of this letter  
Final Report Submission: Within 24 months of the date of this letter

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled “**Postmarketing Study Protocol**”, “**Postmarketing Study Final Report**”, or “**Postmarketing Study Correspondence.**”

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Immunologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,  
and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-618 for this drug product, not to NDA 21-681 or NDA 21-682. In the future, do not make submissions to NDA 21-681 or NDA 21-682 except for the final printed labeling requested above.

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at [www.fda.gov/medwatch/report/mmp.htm](http://www.fda.gov/medwatch/report/mmp.htm).

If you have any questions, please call Christina H. Chi, Ph D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

*{See appended electronic signature page}*

NDA 21-618  
NDA 21-681  
NDA 21-682

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Mark J. Goldberger, M.D., M.P.H.,  
Director  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Enclosure