CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-881

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-881

Norgine International Limited
Attention: Marilyn R. Carlson, D.M.D., M.D., RAC
US Agent
entreMeDica, Inc.
1229 Caminito Graciela
Encinitas, California 92024

Dear Dr. Carlson:

Please refer to your new drug application (NDA) dated June 7, 2005, and received June 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Moviprep (PEG 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid) for oral solution.

We acknowledge receipt of your submissions dated June 2, 2006 and July 25, 2006.

The June 2, 2006 submission constituted a complete response to our April 10, 2006 action letter.

This new drug application provides for the use of Moviprep for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.

We completed our review of this application, as amended. It is 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), and/or submitted labeling (immediate container and carton labels submitted August 2, 2006). Marketing the product(s) 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 this submission "**FPL for approved NDA 21-881**." Approval of this submission 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 are waiving the pediatric study requirement for this application.

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 this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

If you have any questions, call Tanya Clayton, Regulatory Health Project Manager, at (301) 796-0871.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (Package Insert)

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Brian Harvey
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