DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-884/S-002

Insmed Incorporated
Attention: Ronald Gunn
Executive Vice President and COO
4851 Lake Brook Drive
Glen Allen, VA 23060

Dear Mr. Gunn:

Please refer to your supplemental new drug application dated March 21, 2006, received March 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IPLEX (mecasermin rinfabate [rDNA origin] injection), 36 mg/0.6 mL.

This "Changes Being Effected" supplemental new drug application provides for changes to the vial and carton labels for IPLEX.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 21, 2006.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 796-1211.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Vial Label
Carton Label

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

/s/

Mary Parks

9/21/2006 02:11:05 PM