DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-884/S-001

Insmed Inc.
Attention: Ronald D. Gunn
Executive VP and COOr
P.O. Box 2400
Glen Allen, VA 23058-2400

Dear Mr. Gunn:

Please refer to your supplemental new drug application dated January 20, 2006, received January 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IPLEX (mecaserman rinfabate [rDNA origin] injection).

We acknowledge receipt of your submissions dated January 24, June 5 and 14, and September 22, 2006.

Your submission of September 22, 2006, constituted a complete response to our May 10, 2006, action letter.

This supplemental new drug application provides for revised storage conditions.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon attached labeling text with the revision listed below.

The storage statement on the carton and vial should state "STORE FROZEN up to 3 months."

The attached carton and container labels are those approved with Supplement -002, approved on September 21, 2006.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed draft labeling.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission **"FPL for approved supplement NDA 21-884/S-001".** Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
Patient Package Insert (Patient Information and Instructions for Use)
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

2/27/2007 02:10:44 PM