DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021839/S-010

SUPPLEMENT APPROVAL

Ipsen Biopharmaceuticals Inc.
Attention: Archana Reddy, MPH, MS
Director, Regulatory Affairs
106 Allen Road, 3rd Floor
Basking Ridge, NJ 07920

Dear Ms. Reddy:

Please refer to your Supplemental New Drug Application (sNDA) dated July 8, 2011, received July 11, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Increlex (mecasermin [rDNA origin] injection) 10mg/mL.

We acknowledge receipt of your amendments dated August 29, 2011, March 12, July 10, August 22, and 31, and September 4, 2012. We also acknowledge receipt of your email dated September 10, 2012, that includes the agreed-upon labeling.

The March 12, 2012, submission constituted a complete response to our January 11, 2012, action letter.

This "Prior Approval" labeling supplemental new drug application provides for revisions to the Dosage and Administration section of the package inset (PI) to include language describing a conversion formula to allow prescribers to convert a dose expressed in mg/kg to units (instead of milliliters) when using syringes with unit markings, and for revision to the Overdosage section of the PI to include language describing a specific case of overdosage in a 3 year old patient. This supplement also provides for conversion tools, consisting of a dosing sheet and a dosing guide.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, dosing sheet, and dosing guide), with the addition of any labeling changes in pending "Changes Being

Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Abolade (Bola) Adeolu, Regulatory Project Manager, at (301) 796-4264.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
Package Insert (PI)
Dosing Sheet and Dosing Guide

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

/s/

MARY H PARKS
09/13/2012