DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-839

Tercica, Inc.
Attention: Ira Wallis
Vice President, Regulatory Affairs
2000 Sierra Point Parkway, Suite 400
Brisbane, CA 94005

Dear Mr. Wallis:

Please refer to your new drug application (NDA) dated February 24, 2005, received February 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INCRELEX™ (mecasermin [rDNA origin] injection), 10 mg/mL.

We acknowledge receipt of your submissions dated May 9, June 29, July 13 and 28, and August 23 and 26, 2005.

This new drug application provides for the use of INCRELEX™ (mecasermin [rDNA origin] injection) for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to growth hormone.

We have 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 (package insert submitted by secure email August 26, 2005**,** patient package insert submitted by secure email August 25, 2005, immediate container and carton labels submitted August 23, 2005). Marketing the products 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 - NDAs*. 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 21-839**." Approval of this submission by FDA is not required before the labeling is used.

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 Metabolism and Endocrinology Products (DMEP) and two copies of both the promotional materials and the package inserts directly to:

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

We note your agreements dated July 28, 2005, to submit the following information: (1) data from [redacted] stability studies on three lots of formulated drug substance stored in [redacted] to establish shelf-life dating for bulk drug substance; (2) results of studies to identify and characterize the additional [redacted]s in certain rhIGF-1 drug product samples stored at 25°C/60% RH; and (3) results of the ongoing preservative effectiveness study.

Mecasermin has been designated as an orphan drug for the indication being approved. Therefore, the pediatric study requirements of the Pediatric Research Equity Act of 2003 do not apply to this application. However, we note that clinical studies were conducted in pediatric patients two years of age and older.

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

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.

Effective immediately, **ALL** regulatory submissions, whether sent by U.S. Postal Service, overnight mail service, or courier, should be sent to the following address. Processing of submissions sent to other addresses may be delayed.

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolism and Endocrinology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, call Enid Galliers, Chief, Project Management Staff, DMEP, at 301-827-6429.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Package Insert (PI)
Patient Package Insert (PPI)
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/

Robert Meyer

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