DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-074

NDA APPROVAL

Biomeasure, Inc.
U.S. Agent for Beaufour Ipsen Pharma
Attention: Steven R. Scott
Senior Director, Regulatory Affairs
27 Maple Street
Milford, MA 01757

Dear Mr. Scott:

Please refer to your new drug application (NDA) dated October 27, 2006, received October 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Somatuline Depot (lanreotide) Injection, 60 mg, 90 mg, and 120 mg.

We acknowledge receipt of your submissions dated November 17 and 29, 2006, and February 2, March 5, 8, 15, 16, and 27, April 17, 18, and 25, June 11, 15, 22, and 27, July 11, 27, and 30 and August 3, 15, 17, 29, and 30, 2007. ----------

This new drug application provides for the use of Somatuline Depot (lanreotide) Injection for the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

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 and with the minor editorial revisions listed below, as agreed-upon via electronic mail between Andrew Slugg, Steven Scott, and William Jones of Biomeasure, Incorporated, and Jennifer Johnson of the Division of Metabolism and Endocrinology Products on August 29, 2007.

All revisions listed below pertain to the carton and container labeling.

1. Please ensure that the three strengths (60 mg, 90 mg, and 120 mg) of Somatuline Depot each use a different color to differentiate among the strengths on all labels and labeling.

2. Revise the product strength of each label to read in terms of total mg/total mL (e.g., 60 mg/XX mL).

3. Revise the statement on the back panel of the carton labeling to read "CONTENTS: This box contains one (1) pre-filled syringe. Each syringe contains lanreotide acetate corresponding to XX mg of lanreotide base per XX mL solution, which is the equivalent of XX mg lanreotide per syringe." Additionally, this statement should be moved to the principal display panel.

4. We recommend using a larger font to increase the prominence of the storage requirements for Somatuline Depot.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels submitted on August 30, 2007, as revised above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-074**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert) submitted on August 30, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-074."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instructions on completing the Form FDA 2253, see page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

Please submit one market package of the drug product when it is available.

METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

REPORTING REQUIREMENTS

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

MEDWATCH-TO-MANUFACTURER PROGRAM

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.

If you have any questions, call Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert, Patient Package Insert, Carton Labels, and Immediate Container Labels

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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/

Robert Meyer

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