DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-058

Indevus Pharmaceuticals, Inc.
Attention: William B. Gray
Vice President, Regulatory Affairs
33 Hayden Avenue
Lexington, MA 02421

Dear Mr. Gray:

Please refer to your new drug application (NDA) dated June 30, 2006, received July 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Supprelin LA (histrelin acetate) subcutaneous implant, 50 mg.

We acknowledge receipt of your submissions dated August 16, September 15, and November 21, 2006, and March 1, 23, 26, 27, April 3, 13, 16, 18, April 23, and May 3, 2007.

This new drug application provides for the use of Supprelin LA (histrelin acetate) subcutaneous implant, 50 mg for the treatment of central precocious puberty.

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.

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 labeling (text for package insert, patient package insert, immediate container and carton labels submitted on May 3, 2007). Marketing the product 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 - NDA*. 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 22-058**." 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 and two copies of both the promotional materials and the package insert directly 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

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 Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

{See appended electronic signature page}

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

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

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/s/

Mary Parks

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