



NDA 21-595

Indevus Pharmaceuticals, Inc.
Attention: Bobby W. Sandage, Jr., Ph.D.
Executive Vice President
99 Hayden Avenue, Suit 200
Lexington, MA 02421-7966

Dear Dr. Sandage:

Please refer to your supplemental new drug application dated January 31, 2005, received February 1, 2005, submitted under section 505/(b) of the Federal Food, Drug, and Cosmetic Act for Sanctura (trospium chloride), 20 mg, twice daily for the treatment of overactive bladder. This supplement provided a proposed patient package insert (PPI).

We also acknowledge receipt of your submissions dated February 24 and 28, 2005.

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 labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient package insert).

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 supplement NDA 21-595/S-001.**" Approval of this submission by FDA is not required before the labeling is used.

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

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If you have any questions, call Jean Makie, M.S., R.D., Sr. Regulatory Project Manager, at 301-827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director,
Division of Reproductive and Urologic Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Margaret Kober
3/11/05 03:49:14 PM
signed for Dr. Shames