



NDA 21-595/S003

Indevus Pharmaceuticals, Inc.
Attention: John Berryman
Vice President, Regulatory Affairs & Pharmaceutical Sciences
33 Hayden Avenue
Lexington, MA 02421-7971

Dear Mr. Berryman:

Please refer to your supplemental new drug application dated November 10, 2006, received November 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Santura™ (trospium chloride), 20 mg twice daily, for the treatment of overactive bladder.

This Changes Being Effected (CBE) supplemental new drug application contained a revised package insert (PI) that addressed a request from the Division that you revise the Post-Marketing Surveillance sub-section of the ADVERSE EVENTS section.

We completed our review of this application. 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 that submitted in your November 10, 2006 submission.

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-003.**" 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).

If you have any questions, call Jean Makie, M.S., R.D., Sr. Regulatory Project Manager, at 301-796-0952.

Sincerely,

{See appended electronic signature page}

Mark Hirsch, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Mark S. Hirsch
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