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*APPLICATION NUMBER:*

**21-595**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-595

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

Dear Dr. Sandage:

Please refer to your new drug application (NDA) dated April 28, 2003, received April 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sanctura™ (trospium chloride) 20 mg Tablets.

We also refer to your submissions dated May 28, June 11 and 13 (two submissions), August 8 and 26, September 30, November 17 and 21 (two submissions), 2003, January 10, 13, 14, 20, 22, 26, and 30 (two submissions), February 2, 6, 10, 11, 18, and 23, March 11, 16, 23, and 30, April 6, 9, and 22, and May 3, 5, 17, 20, 24, and 25, 2004.

This new drug application provides for Sanctura™ (trospium chloride) 20 mg Tablets for the treatment of overactive bladder associated with symptoms of urge urinary incontinence, urgency, and urinary frequency.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the physician insert and patient package insert) and to the immediate container and carton labels submitted on May 20, 2004.

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 21-595." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric studies for ages 4 and below and are deferring pediatric studies for ages 5 to 15 years for this application.

Your deferred pediatric studies required under Section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. This commitment is listed below.

A pediatric study under PREA for the treatment of overactive bladder in pediatric patients ages 5-15.

Protocol Submission:	by June, 2004
Study Start:	by January, 2005
Final Report Submission:	by December, 2005

Submit clinical protocols to your IND for this product. Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "Required Pediatric Study Commitments".

In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study.

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

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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](http://www.fda.gov/medwatch/report/mmp.htm).

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 Reproductive and Urologic Drug Products (HFD-580) and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising,  
and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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

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

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, please call Ms. Dale Cutright, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Florence Houn, M.D., M.P.H.  
Director  
Office of Drug Evaluation III (HFD-103)  
Center for Drug Evaluation and Research

Enclosure