

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

NDA 22-103

**RISK ASSESSMENT and RISK MITIGATION
REVIEW(S)**

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 15, 2007

TO: Scott Monroe, M.D., Acting Director
Division of Reproductive and Urologic Products

VIA: Jean Makie, Regulatory Health Project Manager
Division of Reproductive and Urologic Drug Products

FROM: Jeanine Best, M.S.N., R.N., P.N.P.
Patient Product Information Specialist
Division of Surveillance, Research, and Communication Support

THROUGH: Toni Piazza-Hepp, Pharm.D., Deputy Director
Division of Surveillance, Research, and Communication Support

SUBJECT: OSE/DSRCS Review # 2 regarding Patient Labeling for Sanctura XR
(trospium chloride extended release) Capsules, NDA 22-103

Background and Summary

Indevus Pharmaceuticals amended their NDA as requested with revised Patient Labeling in the form of a Patient Package Insert (PPI) on April 30, 2007, for Sanctura XR (trospium chloride extended release) Capsules, NDA 22-103. The PPI was submitted as section 17, Patient Counseling Information, of the Full Prescribing Information (FPI).

Refer to the OSE/DSRCS PPI review dated March 28, 2007. We recommended that the sponsor revise and resubmit a draft PPI for Sanctura XR

Comments and Recommendations

↓ ↓ ↓

Please call us if you have any questions.

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/s/

Jeanine Best
5/15/2007 02:57:45 PM
DRUG SAFETY OFFICE REVIEWER

Toni Piazza Hepp
5/15/2007 03:27:30 PM
DRUG SAFETY OFFICE REVIEWER

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: April 20, 2007

TO: Scott Monroe, M.D., Acting Director
Division of Reproductive and Urologic Products

VIA: Jean Makie, Regulatory Health Project Manager
Division of Reproductive and Urologic Drug Products

FROM: Jeanine Best, M.S.N., R.N., P.N.P.
Patient Product Information Specialist
Division of Surveillance, Research, and Communication Support

THROUGH: Toni Piazza-Hepp, Pharm.D., Deputy Director
Division of Surveillance, Research, and Communication Support

SUBJECT: OSE/DSRCS memo regarding Patient Labeling for _____ (trospium chloride extended release) Capsules, NDA 22-103

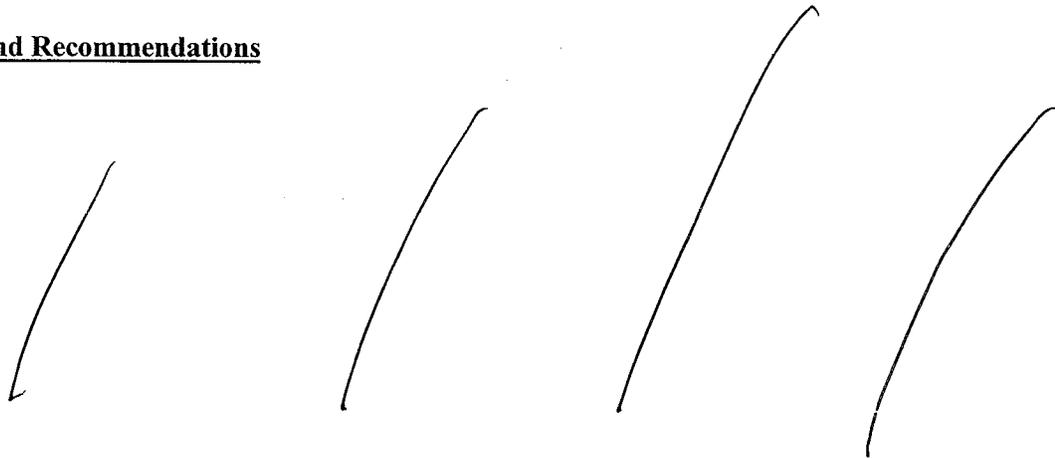
Background and Summary

Indevus Pharmaceuticals submitted a NDA on October 12, 2006, for _____ (trospium chloride extended release) Capsules, NDA 22-103, for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. This NDA is a line extension to the currently approved 20-mg twice-daily tablet formulation of trospium chloride, which is marketed under the name Sanctura (NDA 21-595, approved 5/04).

Submitted labeling includes Full Prescribing Information (FPI) in the new PLR format and patient labeling in the form of a Patient Package Insert (PPI) submitted on March 19, 2007.

OSE/DSRCS was asked to review the PPI.

Comments and Recommendations



Please call us if you have any questions. We will be glad to review a revised draft PPI for _____

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/s/

Jeanine Best
4/20/2007 08:26:32 AM
DRUG SAFETY OFFICE REVIEWER

Toni Piazza Hepp
4/20/2007 04:59:42 PM
DRUG SAFETY OFFICE REVIEWER

MEMORANDUM

**Division of Medication Errors and Technical Support
Office of Surveillance and Epidemiology
WO 22, Mailstop 4447, HFD-420
Center for Drug Evaluation and Research**

To: Scott Monroe MD
Acting Director, Division of Reproductive and Urologic Products, HFD-580

Through: Todd Bridges, RPh, Team Leader
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

From: Kimberly Pedersen, RPh, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

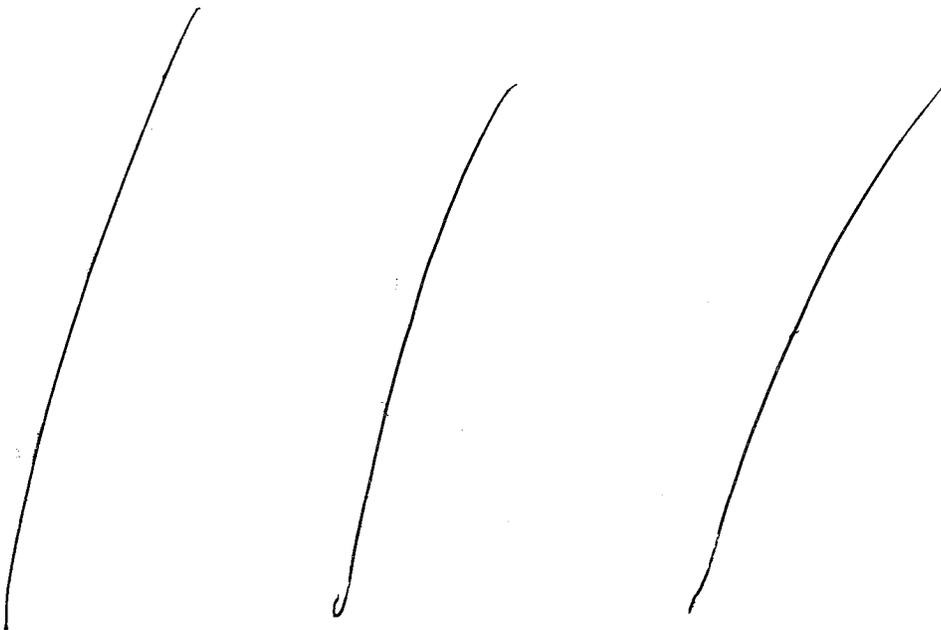
Date: July 2, 2007

Subject: OSE Review 2007-1457
Proprietary Names: Sanctura XR
Trospium Chloride Extended-release Capsules
60 mg
Sponsor: Indevus Pharmaceuticals, Inc.
NDA #: 22-103

This memorandum is in response to a June 29, 2007 request from your Division for a review of the proposed labels and labeling for Sanctura XR.

DMETS has evaluated the labels and labeling from a medication error perspective and we have identified the following areas of needed improvement to minimize potential error.

A. GENERAL COMMENTS



1 Page(s) Withheld

 Trade Secret / Confidential

 ✓ Draft Labeling

 Deliberative Process

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/s/

Kimberly Culley-Pedersen
7/27/2007 12:32:09 PM
DRUG SAFETY OFFICE REVIEWER

Todd Bridges
7/27/2007 01:22:18 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
7/27/2007 02:15:43 PM
DRUG SAFETY OFFICE REVIEWER