CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 22-103

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO 22, MAIL STOP 4447)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**OSE REVIEW #:**
December 21, 2006	March 12, 2007	2006-1115 and 2007-523
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October 12, 3006	August 13, 2007	

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

THROUGH: Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

FROM: Kimberly Pedersen, R.Ph., Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME:	**SPONSOR: Indevus Pharmaceuticals**
[redacted] **Sanctura XR (secondary)** Trospium Chloride Extended-release Capsules [redacted] 60 mg **NDA#: 22-103**	

COMMENDATIONS:
DMETS does not recommend the use of the proprietary name [redacted]

DMETS does not object to the use of the proprietary name, Sanctura XR. We acknowledge the potential for error on initial introduction to the marketplace with Sanctura. However, Sanctura and Sanctura XR do not share overlapping strengths or dosing frequency, which may help to limit this confusion and error. Despite these differences, DMETS would still recommend the sponsor institute an educational program to help practitioners be aware of the presence of the new extended-release product. In addition, DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review in order to minimize potential errors with the use of this product. The name must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary or established names from the signature date of this document.

2. DDMAC finds the proprietary name o[redacted]nd Sanctura XR acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. Please copy DMETS on any communication to the sponsor with regard to this review. If you have further questions or need clarifications, please contact Cherye Milburn, Project Manager, at 301-796-2084.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
WO 22, MAIL STOP 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: January 31, 2007

NDA #: 22-103

NAME OF DRUG: —

Sanctura XR (secondary)
(Trospium Chloride Extended-release Capsules)
— 60 mg

NDA SPONSOR: Indevus Pharmaceuticals

NOTE: This review contains proprietary and confidential information that should not be released to the public.

I. INTRODUCTION

This consult was written in response to a request from the Division of Reproductive and Urologic Products for assessment of the proprietary names ' — and "Sanctura XR", regarding potential name confusion with other proprietary or established drug names. Insert labeling, draft container, and draft blister pack labels were provided for review and comment.

Sanctura represents an addition to the Sanctura drug product line. ' — /Sanctura XR contains trospium chloride as extended-release capsules in — 60 mg strengths. — Sanctura XR is indicated for the treatment of overactive bladder with symptoms of urge incontinence, urgency, and urinary frequency. The recommended dosage for — Sanctura XR is 60 mg daily in the morning with water on an empty stomach. — The capsules are proposed to be packaged in 30 ' — count bottles.

The currently marketed Sanctura is indicated for the treatment of overactive bladder with symptoms of urge incontinence, urgency, and urinary frequency and available as a 20 mg tablets. The recommended dosage is 20 mg twice daily on an empty stomach. For patients with severe renal impairment, the dose is 20 mg once daily at bedtime. The 20 mg tablets are packaged in 60 count bottles.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of the internet, several standard published drug product reference texts[i,ii] as well as several FDA databases[iii,iv] for existing drug names which sound-alike or look-alike to [redacted] Sanctura XR to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[v]. The Saegis[vi] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a drug must be considered in the overall safety evaluator risk assessment.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Sanctura XR. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff with representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC finds the proprietary names [redacted] and Sanctura XR acceptable from a promotional perspective.

2. The Expert Panel identified [redacted] as having the potential for confusion with [redacted]. Independent investigation identified three additional names (Ambien CR, Dantrium, and Femtrace) as having potential for confusion with Sanctura XR. These products along with the available dosage form(s) and usual dosage is listed in Table 1 (see page 4 and 5).

3. [redacted]

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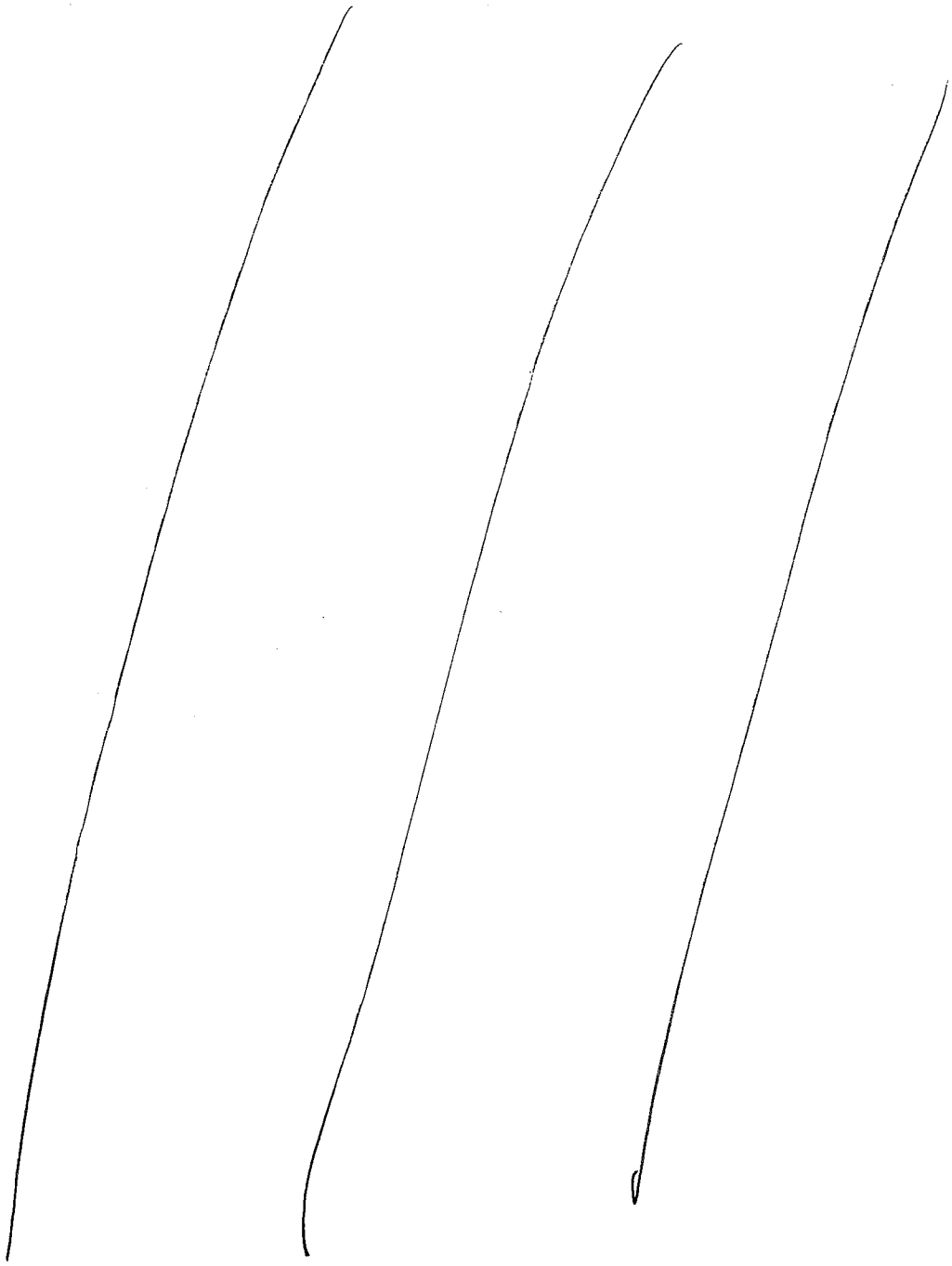
[i] MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[ii] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[iii] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.
[iv] Phonetic and Orthographic Computer Analysis (POCA)
[v] WWW location http://www.uspto.gov/tmdb/index.html.
[vi] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

4. The Expert Panel identified seven names (Sanctura, Cardura XL, Sustiva, Gantrisin, Senokot XTRA, Gentiana 12, and Sarafem) as having the potential for confusion with Sanctura XR. Independent investigation identified nine additional names (Cardizem SR, Aerolate JR/SR, Gantanol DS, [redacted], Dantrium, Femtrace, Fentora, and Ganidin NR) as having potential for confusion with Sanctura XR. Two proprietary names were identified by [redacted] (Ganituss NR, Ganituss DM NR). These products along with the available dosage form(s) and usual dosage is listed in Table 2 (see page 5 and 6).



Product Name	Established name, Dosage form(s)	Usual adult dose*	Other**

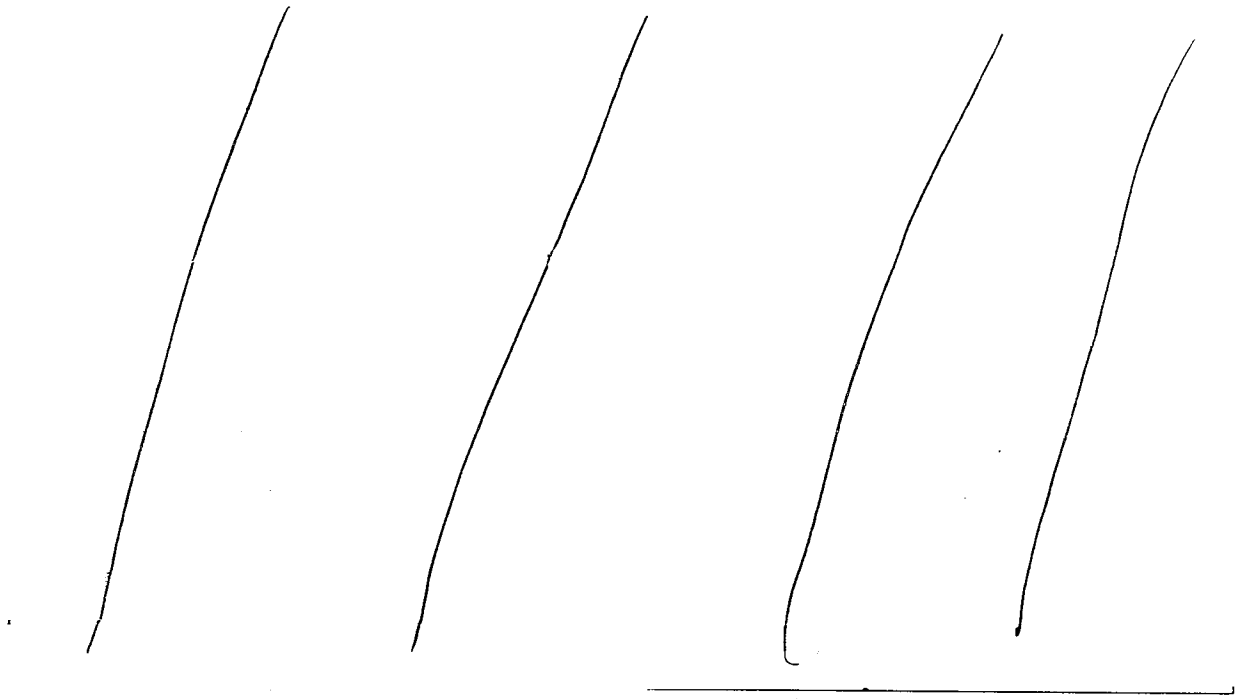


Table 2: Potential Look-Alike and Sound-Alike Names Identified for Sanctura XR

Product Name	Established name, Dosage form(s)	Usual adult dose*	Other**
Sanctura XR	Trospium Chloride Extended-release Capsules, 60 mg	60 mg daily on an empty stomach	
Sanctura	Trospium Chloride Tablets, 20 mg	20 mg twice daily.	LA/SA
Cardura XL	Doxazosin Mesylate Extended-release Tablets 4 mg and 8 mg	One daily.	LA/SA
Cardizem SR (discontinued, generics avialable)	Diltiazem Hydrochloride Extended-release Capsules 60 mg, 90 mg, 120 mg, 180 mg	Twice daily.	LA
Aerolate JR SR	Theophylline Extended-release Capsules 130 mg 260 mg	10 mg/kg/day in divided doses (Every 8 to 12 hours),	LA
Gantanol DS (discontinued, but generics available)	Sulfamethoxazole Tablets, 500 mg and 1 gram	Adults: 1 to 2 grams every 8 to 12 hours. Children: 25-60 mg/kg every 12 hours	LA
			LA

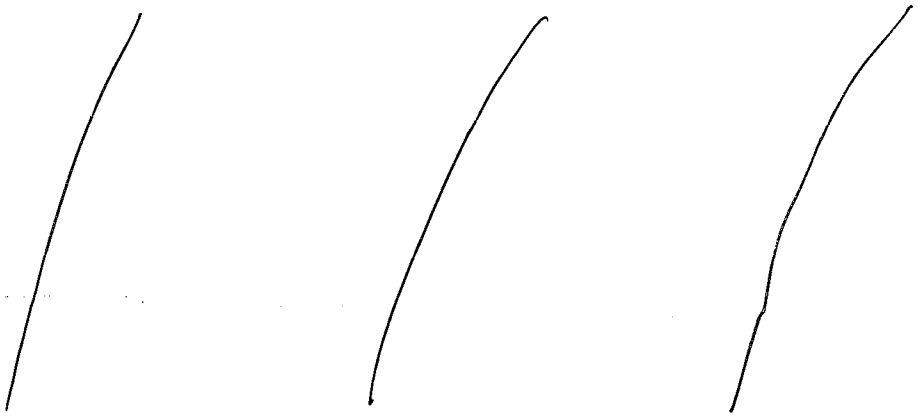
Product Name	Established name, Dosage form(s)	Usual adult dose*	Other**
Sanctura XR	Trospium Chloride Extended-release Capsules, [redacted] 60 mg	60 mg daily on an empty stomach	
Dantrium	Dantrolene Sodium Capsule: 25 mg, 50 mg, and 10 mg Injection: 20 mg per vial	Chronic Spasticity: Adults: 25 mg daily for seven days, then 25 mg three times daily for seven days , then 50 mg three times daily for seven days, then 100 mg three times daily. Children: 0.5 mg/kg daily for seven days, then 0.5 mg/kg three times daily for seven days, then 1 mg/kg three times daily for seven days, then 2 mg/kg three times daily. Malignant Hyperthermia: 4 to 8 mg/kg daily in three to four divided doses one to two days before surgery.	LA
Femtrace	Estradiol Acetate Tablets, 0.45 mg, 0.9 mg, and 1.8 mg	One tablet daily.	LA
Fentora	Fentanyl Citrate Buccal Tablet, 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg	Starting dose of 100 mcg, then titrate for efficacy. The dose may be repeated once curing a single episode of breakthrough pain if not adequately treated.	LA
Sustiva	Efavirenz Capsules: 50 mg, 100 mg, and 200 mg Tablets: 600 mg	600 mg daily.	LA
Gantrisin (Pediatric)	Sulfisoxazole Acetyl Suspension, 500 mg/5 mL	One-half of the 24 hours dose for the initial dose. Maintenance dose: 150 mg/kg/24 hours, which can be divided in 4 to 6 doses. Should not exceed 6 grams in 24 hours.	LA
Ganidin NR	Guaifenesin Liquid 100 mg/5 mL	25 mg to 400 mg every 4 hours.	LA
Senokot XTRA	Sennosides Tablets, 17.2 mg	Adults: One tablet daily to a maximum of 2 tablets twice daily. Children 6 -12 years: ½ tablet daily to one tablet twice daily.	LA
Gentiana 12	Gentiana, Moutan, Plantago seed, Bupleurum, Sophora, Rehmannia, Tang Kuei, Scute, Gardenia, Coptis, Kdsurea Bark, Licorice Pin Yin longdancao, mudanpi, cheqianzi, chaihu, kushen, shengdi, danggui, huangqin, zhizi, huanglian, zijingpi, gancao	Unable to find.	LA
Sarafem	Fluoxetine Hydrochloride Capsule:10 mg and 20 mg	20 mg daily.	LA
Gani-Tuss NR	Codeine Phosphate and Guaifenesin Liquid 10 mg, 100 mg in 5 mL	10 mL every 4 hours, up to 60 mL per day.	LA
Gani-Tuss DM NR	Dextromethorphan Hydrobromide and Guaifenesin Liquid, 10 mg and 100 mg in 5 mL	10 mL every 4 hours, up to 60 mL per day	LA

*Frequently used, not all-inclusive.
**LA (look-alike)/SA (sound-alike).
***Proprietary and Confidential Information that should not be released to the public.

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

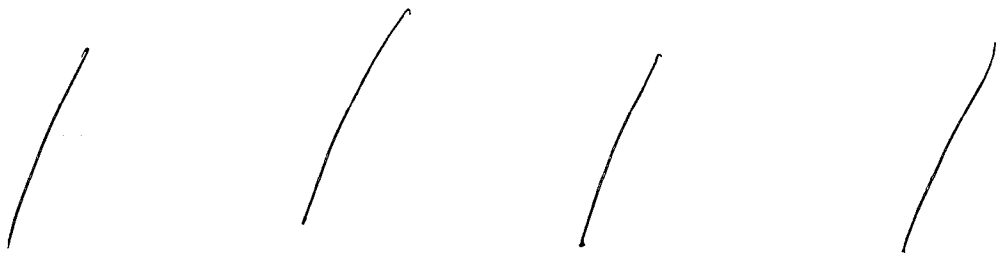
Three separate studies were conducted within the Centers of the FDA for each of the proposed proprietary names to determine the degree of confusion of [redacted] and Sanctura XR with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 123 health care professionals (pharmacists, physicians, and nurses). The exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and an outpatient prescription were written, each consisting of a combination of marketed and unapproved drug products with a prescription for [redacted] and Sanctura XR (see below). These prescriptions were optically scanned and one prescription was delivered to a random sample of participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail and sent to a random sample of participating health professionals for their interpretation and review. After receiving either written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.



Sanctura XR

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Sanctura XR #15 Tag po qam	Sanctura XR Number 15 One capsule orally in the morning
Inpatient RX: Sanctura XR 1 cap qam po	

2. Results for [redacted]



3. Results for Sanctura XR:

One respondent from the inpatient study interpreted the proposed name as Ganituss. Gani-Tuss NR and Gani-Tuss DM NR are marketed generic products in the US marketplace. Four inpatient participants interpreted the modifier as "PR" and two voice participants interpreted "SR." The abbreviation "PR" is a medical abbreviation for 'per rectum.' See Appendix B for complete listing of interpretations from the verbal and written studies.

C. FDA AERS and DQRS DATABASE SEARCHES

[redacted] Sanctura XR is an addition to the currently marketed, Sanctura product line. As this drug product was approved in May 2004, DMETS performed a search of the FDA AERS and DQRS databases for any medication errors. For AERS, the following criteria were used: MEDDRA High Level Group Term (HLGT) "Medication Errors" and Preferred Term (PT) Pharmaceutical Product Complaint with the active ingredient, tradename and verbatim letter string of "Sanc%[vii]" and "Trosi%." These searches found no cases involving medication errors with nomenclature, labels, labeling, and packaging. In addition, a search of the DQRS database with the criteria of "%Sanctura%" or tradename like "%trospium%" found no reports involving Sanctura.

D. SAFETY EVALUATOR RISK ASSESSMENT

To evaluate the potential of medication error with the proposed names [redacted] and "Sanctura XR", DMETS will review certain aspects that commonly lead to error with drug name extensions. Some characteristics that often cause error are associations or misinterpretations of the modifier, the potential for confusion with the currently marketed product line (immediate release Sanctura), and the potential for proprietary name confusion with drug products currently marketed.

[redacted] **Name Evaluation**

[vii] A wildcard term used in database searching (%).

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Sanctura XR Name Evaluation

1. Examination of the "XR" modifier

   When reviewing the proposed "XR" modifier, DMETS must not only evaluate the orthographic or phonetic similarity between the currently marketed products and the proposed modifier, but also examine if the meaning of the modifier is consistent with current "XR" products, if the modifier is ambiguous, and if the "XR" can look like a number, be interpreted as directions for use or is similar to a medical abbreviation. Finally, one must evaluate if the addition of the modifier makes the name look similar to another drug name.

   a. When evaluating the appropriateness of the modifier and the intended meaning, we discovered

twenty prescription products listed in the Orange Book, drugs@FDA, and DSS that use the "XR" modifier [Adderall XR, Augmentin XR, [redacted] Cipro XR, Dilacor XR[+], Dilt-XR[+], Effexor XR, Focalin XR, Glucophage XR, [redacted] Lodrane XR[+], [redacted][***], Proquin XR[+], Seroquel XR[***], Tanacof XR[+], Tegretol XR, Tusso-XR[+], Voltaren XR, Xanax XR, and Zerit XR (discontinued)].

Most of the "XR" drugs that represent product line extensions or proprietary names generics of product line extensions are dosed once daily (n=15) with the remaining five dosed twice daily/three times daily (n=5). Of the five drug products not dosed once daily, three were monograph drug products (Tanacof XR, Tusso-XR, Lodrane XR), and one (Tegretol XR) was approved in 1996 and thus not reviewed by DMETS. The remaining name, Augmentin XR, was reviewed by DMETS and approved by the Agency in 2002. Unfortunately, the name Augmentin XR was reviewed prior to the release of the Institute of Medicine report "Preventing Medication Errors" (2006) [xv] or the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) meeting on "Drug Name Suffixes and Medication Errors" (2005) [xvi] which identified safety concerns with modifiers. Since this, DMETS is addressing these issues in current review practices.

Despite the fact that 5 products have twice-daily dosing and use the 'XR' modifier, in DMETS opinion, the XR modifier adequately captures the most notable difference between Sanctura XR and Sanctura, which is the dosing interval. As such, DMETS concludes that the 'XR' modifier is an acceptable choice for the proposed product from this perspective.

b. In analysis of the potential for the "XR" modifier to resemble any numbers, dosing instructions, or medical abbreviation, post-marketing reporting has found that "XR" has been misinterpreted as "x 2." This confusion occurred when the first XR suffix was approved. We have not seen recent confusion and this abbreviation do not appear on the dangerous abbreviations list. Additionally, the modifier "XR" is identified by standard references[xvii] as extended-release, X-linked recessive, X-ray, and Xeroradiography. These interpretations should not result in confusion. Moreover, the "X" of XR is associated with the Roman numeral "ten" and "R" could be misinterpreted as the Roman numeral "L"; thus, XL or "40". However, we have not had such reports of confusion. Despite the potential for the "XR" modifier to look or be defined as above, DMETS does not believe this would prohibit the use of this modifier.

2. Potential for Product Line Confusion

The Potential for Product Line Confusion and Look-alike Name Confusion concerns for the "XR" modifier are the same as those for [redacted] as stated above in Sections II-D-2. Therefore, DMETS will not discuss these issues in detail.

3. Look-Alike And Sound-Alike Concerns

In reviewing the proprietary name, Sanctura XR, the eighteen names identified as having a similar appearance and sound to Sanctura XR are the existing Sanctura tablets, [redacted]

[***] Proprietary and confidential information that should not be released to the public.

[xv] July 20, 2006, Institute of Medicine (IOM) Report "Preventing Medication Errors" recommendation number four

[xvi] NCC MERP meeting "Drug Name Suffixes and Medication Errors: Exploring the Relationship and Minimizing the Risk". October 2005.

[xvii] http://www.pharma-lexicon.com/, 02May2007.

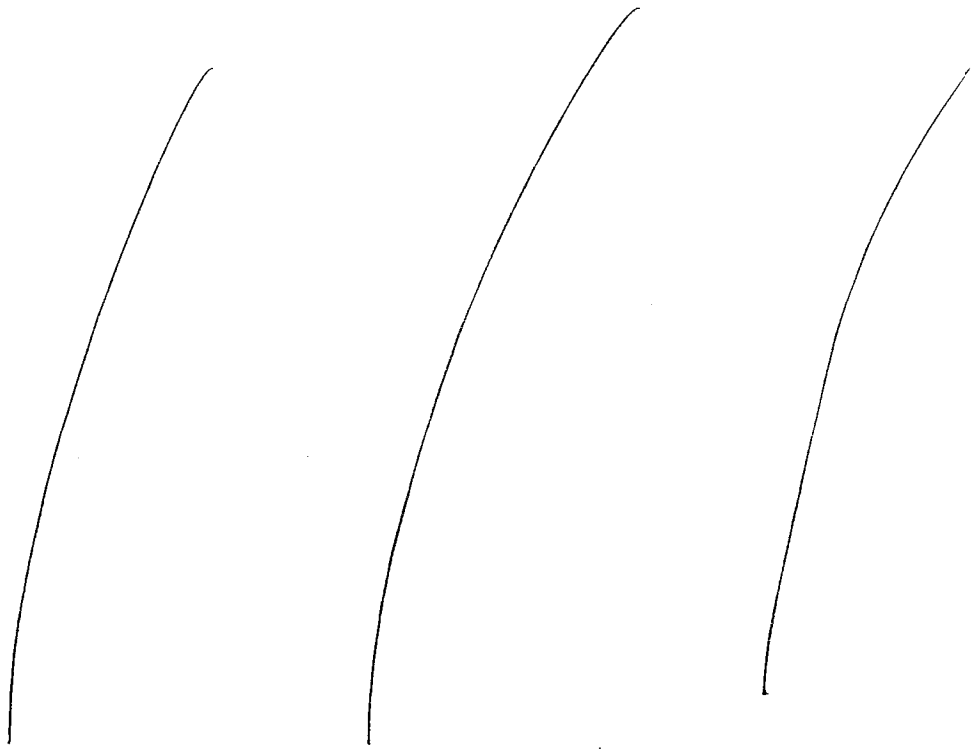
Cardura XL, Cardizem SR, Gantanol DS, ——— , Aerolate JR and SR, Dantrium, Femtrace, Fentora, Sustiva, Gantrisin, Ganidin NR, Senokot XTRA, Gentiana 12, Sarafem, Gani-Tuss NR, and Gani-Tuss DM NR.

Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was confirmation that Sanctura XR could be confused with Gani-Tuss NR and Gani-Tuss DM NR. One respondent from the inpatient study misinterpreted the name for an already existing marketed drug product. Four inpatient participants interpreted the modifier as "PR" and two voice participants interpreted the modifier as "SR." The abbreviation "PR" can be interpreted as 'per rectum.' Thus, DMETS conducted as review of pharmacy references (e.g. Facts and Comparisons) to determine if any products administered rectally had a proprietary name or reference that could lead to confused with Sanctura XR. This search found no names that had look-alike appearance to Sanctura XR. The remaining misinterpretations were misspelled/phonetic variations of the proposed name, Sanctura XR.

Of the eighteen names identified as having similar appearance and sound, the following twelve names will not be reviewed further due to weak orthographic similarities, weak phonetic similarities, lack of availability in the marketplace, control status, prescription status, and/or lack of overlapping products characteristics such as dosage form, strength, and/or directions for use: Cardura XL, Cardizem SR, Gantanol DS, Aerolate JR and SR, Femtrace, Fentora, Sustiva, Gantrisin, Ganidin NR, Senokot XTRA, Gentiana 12, and Sarafem. The potential for confusion with Sanctura and Sanctura XR was evaluated above (Section II D 2 a).

The remaining names are discussed below.

*** Proprietary and confidential information that should not be released to the public.



c. Dantrium may look similar to Sanctura XR when scripted. Dantrium contains dantrolene sodium in capsules and as an injectable. The capsules are available as 25 mg, 50 mg, and 100 mg strengths, with the injectable in 20 mg per vial. Dantrium is indicated for chronic spasticity with recommended dosing ranging from 25 mg daily to 100 mg three times daily for adults and 0.5 mg daily to 2 mg/kg three times daily in children. Dantrium is also indicated for malignant hyperthermia where the recommended dosing is 4 to 8 mg/kg in three to four divided doses.

Look-alike similarities between Dantrium and Sanctura XR may be attributed to the potential for the leading "D" and "S" to resemble and the shared central "t." However, the concluding "m" of Dantrium may differentiate as well as the "XR" modifier of Sanctura.

Dantrium Sanctura XR

Sanctura XR and Dantrium share the overlapping characteristics of oral dosage form, daily dosing frequency (at the beginning of titration of Dantrium). Post-marketing reports found no confusion with the currently marketed Sanctura immediate-release drug product and Dantrium. Thus, the likelihood of simultaneous misinterpretation of the name is limited. Thus, DMETS believes the likelihood of confusion is minimal.

d. Gani-Tuss NR and Gani-Tuss DM NR may look similar to Sanctura XR when scripted. One

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Proprietary and confidential information that should not be released to the public

*** Proprietary and confidential information that should not be released to the public

participant of the inpatient prescription studies interpreted the name as 'Ganituss.' Gani-Tuss NR contains Codeine Phosphate (10 mg) and Guaifenesin (100 mg) Liquid per 5 mL and Gani-Tuss DM NR contains dextromethorphan hydrobromide (10 mg) and guaifenesin (100 mg) per 5 mL. Each is dosed at 10 mL every 4 hours, which can be administered up to 60 mL per day.

Look-alike similarities between Gani-Tuss and Sanctura XR may be attributed to the potential for the leading "G" and "S" to resemble when scripted, the shared central "t", and the potential for the modifier "NR" to resemble "XR." However, the concluding double "s" of Gani-Tuss may distinguish the names.

Ganituss NR

Ganituss DMNR Sanctura XR

Sanctura XR and Gani-Tuss NR/DM NR share the overlapping characteristic of oral ingestion, but differ in dosage form (capsules compared with liquid). The products differ in all other product characteristics as follows: strength (—— 60 mg compared to 10 mg/100 mg per 5 mL), dosing frequency (daily compared to every 4 hours), and dispensing amount (tablet count compared to milliliters), and the dose unit of measure (tablet compared to teaspoonful/milliliter). Due to the differing product characteristics, DMETS believes the possibility to be minimal.

III. COMMENTS TO THE SPONSOR

DMETS has no objections to the use of the proprietary name, Sanctura XR. However, DMETS does not recommend the use of the proprietary name —— . Specifically, we object to ~~~~

[ii] http://www.drugstore.com/products/prod.asp?pid=143158&catid=47743&trx=PLST-0-SEARCH&trxp1=47743&trxp2=143158&trxp3=1&trxp4=0&btrx=BUY-PLST-0-SEARCH, 20 Mar 2007.

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Additionally, DMETS reviewed the labels and labeling from a safety perspective. DMETS focused on safety issues relating to possible medication errors and have identified these areas of possible improvement in the interest of patient safety.

A. GENERAL COMMENTS

B. CONTAINER LABELING

C. INSERT LABELING

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Appendix B: Prescription Study Results for Sanctura XR

Inpatient	Outpatient	Voice
Ganituss XR	Sanctura XR	Sanctera XR
Sanctura XR	Sanctura XR	Versinc Terra XR
Sanctus XR	Sanctura XR	Santura XR
Ganatura (Sanatura) PR	Sancture XR	Sanctura XR
Sanestus PR	SANCTURA XR	Sanctura SR
Sanctura XR	Sanctura XR	Sanctura SR
Sanctura XR	Sanctura XR	St.Ketera XR
Sanctus XR	Sanctura XR	
Sanitua PR	Sanctura XR	
Sanctva PR	Sanctura XR	
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