

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-479

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(WO 22, Mailstop 4447)

DATE RECEIVED: May 16, 2006 DATE OF DOCUMENT: December 13, 2005 and March 29, 2005	DESIRED COMPLETION DATE: June 11, 2006 PDUFA DATE: June 14, 2006	OSE REVIEW #: 02-0065-4
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TO: Russell Katz, M.D.
Director, Division of Neurology Products
HFD-120

THROUGH: Alina Mahmud, RPh., MS, Team Leader
Denise Toyer, Pharm D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Linda M. Wisniewski, RN, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: Zelapar
(Selegiline Hydrochloride) Orally Disintegrating Tablets
1.25 mg

NDA#: 21-479

NDA SPONSOR: Valeant Pharmaceuticals

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Zelapar. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.
2. DMETS recommends implementation of the labels and labeling revisions outlined in section II of this review to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, Zelapar, 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. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

**Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
WO 22; Mailstop 4447
Center for Drug Evaluation and Research**

PROPRIETARY NAME REVIEW

DATE OF REVIEW: May 17, 2006

NDA#: 21-479

NAME OF DRUG: Zelapar
(Selegiline Hydrochloride) Orally Disintegrating Tablets
1.25 mg

NDA HOLDER: Valeant Pharmaceuticals

I. INTRODUCTION:

This consult was written in response to a request from the Division of Neurology Products (HFD-120), for a re-assessment of the proprietary name, "Zelapar", regarding potential name confusion with other proprietary or established drug names. The name Zelapar was found acceptable by DMETS in ODS consult #'s: 02-0065, dated July 5, 2002; 02-0065-1 dated July 31, 2003; 02-0065-2 dated September 14, 2005 and 02-0065-3 dated January 26, 2006. Additionally, the sponsor submitted two versions of container labels, carton and insert labeling which were identified by the sponsor as Campaign 1 and Campaign 2.

PRODUCT INFORMATION

Zelapar Orally Disintegrating Tablets contain selegiline hydrochloride, a levorotatory acetylenic derivative of phentylamine. Zelapar is available for oral administration (not to be swallowed) in a strength of 1.25 mg. It is indicated as an adjunct in the management of patients with Parkinson's disease being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy. Treatment should be initiated with 1.25 mg given once a day for at least six weeks. After six weeks, the dose may be escalated to 2.5 mg given once a day if a desired benefit has not been achieved and the patient is tolerating Zelapar. Zelapar is supplied in a moisture-resistant pouch containing ten tablets and packaged in a child-resistant carton containing six pouches. Tablets are to be used within three months of opening the pouch and immediately upon opening individual blisters. The blisters should be stored in the pouch. Potency cannot be guaranteed after three months of opening the pouch.

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II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts^{1,2} as well as several FDA databases^{3,4} for existing drug names which sound-alike or look-alike to Zelapar 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 conducted⁵. The Saegis⁶ 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.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Zelapar. 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 and 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 name, Zelapar, acceptable from a promotional perspective.
2. The Expert Panel identified two additional proprietary names that were thought to have the potential for confusion with Zelapar. These products are listed in Table 1 (see below), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel.

Product Name	Dosage form(s); Established name	Usual adult dose*	Other**
Zelapar	Selegeline HCl Orally Disintegrating Tablets 1.25 mg	1.25 mg to 2.5 mg once a day	NA
Betapar	Meprednisone Tablets: 4 mg	No dosing information available.	LA
Betapace	Sotalol HCl Tablets: 80 mg 120 mg, 160 mg, and 240 mg	80 mg to 320 mg twice daily.	LA

*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)

¹ 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.

² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

³ AMF Decision Support System [DSS], Drugs@FDA, the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, and the electronic online version of the FDA Orange Book.

⁴ Phonetic and Orthographic Computer Analysis

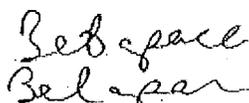
⁵ WWW location <http://www.uspto.gov/tmdb/index.html>.

⁶ Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Zelapar, the primary concerns related to look-alike and/or sound-alike confusion with Betapar and Betapace. However, upon further review of the names gathered from EPD, the name Betapar will not be reviewed further because the product was withdrawn in 1995 and there are no generics currently available.

Betapace has been identified as a name that may look similar to Zelapar when written. Betapace is indicated in the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that in the judgment of the physician are life-threatening. Both names begin and end with letters that may look similar when scripted (Zela vs. Beta and apar vs. apace) (see below). Although Betapace contains a cross-bar for the 't', this may not be a significant differentiating factor. Despite the orthographic similarities, there are some differentiating product characteristics that may help to distinguish between these two products. They include dose (1.25 mg vs. 80 mg to 320 mg), frequency of administration (once daily vs. twice daily), and strength (1.25 mg vs. 80 mg, 120 mg, 160 mg, and 240 mg). An order for Zelapar may omit the strength since it is supplied in only one strength, however, an order for Betapace would need to include a strength for accurate dispensing. This additional information would help to mitigate an error. Therefore, despite the potential for orthographic similarities, the dose, strength, and dosing frequency will help to minimize confusion involving this name pair.



III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In the review of the container labels, carton and insert labeling of Zelapar, DMETS has attempted to focus on safety issues relating to possible medication errors. The following recommendations pertain to Campaign 2 labels and labeling.

A. GENERAL COMMENTS

DMETS previously reviewed Campaign 1 labels and labeling on September 14, 2005 (see ODS consult 02-0065-2) at which time label and labeling recommendations were forwarded to the Division. Campaign 2 labels and labeling incorporate many of DMETS recommendations from the Campaign 1 submission. The sponsor has plans on using Campaign 1 labels and labeling at the initial launch of Zelapar. Campaign 2 labels will then be used once supply of Campaign 1 labeling and packaging is exhausted. Therefore, the sponsor's proposal to utilize both Campaign 1 and 2 labeling is of concern since the Campaign 1 labels do not incorporate DMETS safety recommendations incorporated in the Campaign 2 labeling.

DMETS recommends that the sponsor utilize only Campaign 2 labels and labeling when marketing this product. DMETS is also concerned that differences in Campaign 1 and 2 labels and labeling will cause confusion once the transition takes place. Specifically, we note that the blister label for Campaign 1 differs from that of Campaign 2 in that Campaign 2 includes directions not to push the tablet through the foil. We also note that the DOSAGE AND ADMINISTRATION Section of the package insert states 'Patients should not attempt to push ZELAPAR through the foil backing.' DMETS has safety concerns about the lack of this information on the blister label for Campaign 1. Particularly, we are concerned about the adverse

events that may occur if the integrity of the tablet is destroyed. If patients are used to dispensing the tablets by pushing the tablet through the foil in Campaign 1 and eventually receive a blister from Campaign 2 that tells them not to push through the foil, they may be confused as to how to dispense the medication. Additionally, the strength is not presented in conjunction with the established name. Moreover, the inclusion of the trademark 'Zydis' on the principal display panel may cause confusion because patients and health care practitioners may believe it is the proprietary name of the product. Finally, the stability of the product could be questioned because there is no statement to identify when the pouch was opened or no statement concerning the storage of the product in the pouch.

B. BLISTER LABEL

1. We recommend the inclusion of the finished dosage form "Orally Disintegrating Tablet" in conjunction with the established name. For example:

Selegiline HCl Orally Disintegrating Tablet

2. The "Rx Only" statement should be moved away from the established name and be made less prominent as it currently has more prominence than the established name and strength.
3. Insert a space in between the numeral "1.25" and the unit designation 'mg' (see arrows below).

Each tablet contains
1.25mg selegiline
hydrochloride

1.25mg selegiline hydrochloride

C. POUCH LABELING

1. Increase the prominence of the strength so that it has equal prominence as the proprietary name.
2. We note that there is a dotted line with a small scissors graphic on the left side of the pouch indicating that scissors are to be used to open the pouch. Due to the indication for use of this product (Parkinson's Disease), we recommend that the pouch be revised to include a perforated edge to allow for hand tearing to open it rather than requiring the use of scissors as this might be a safety hazard for someone with Parkinson's Disease.

D. CARTON LABELING

See comment C1.

E. INSERT LABELING

No comments.

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this page is the manifestation of the electronic signature.**

/s/

Linda Wisniewski
6/2/2006 03:08:18 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
6/2/2006 03:53:21 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
6/2/2006 04:11:00 PM
DRUG SAFETY OFFICE REVIEWER

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CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)**

DATE RECEIVED: June 7, 2005	DESIRED COMPLETION DATE: July 28, 2005	ODS CONSULT #: 02-0065-2
DATE OF DOCUMENT: March 29, 2005	PDUFA DATE: September 30, 2005	
TO: Russell Katz, MD Director, Division of Neuropharmacological Drug Products HFD-120		
THROUGH: Teresa Wheelous Project Manager HFD-120		
PRODUCT NAME: Zelapar (Selegiline Hydrochloride) Orally Disintegrating Tablets 1.25 mg NDA#: 21-479	NDA SPONSOR: Elan Pharmaceuticals	
SAFETY EVALUATOR: Kimberly Culley, RPh		
RECOMMENDATIONS: 1. DMETS has no objections to the use of the proprietary name, Zelapar from a safety perspective. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.		
2. DMETS recommends implementation of the label and labeling revision outlined in section III of this review to minimize potential errors with the use of this product.		
3. DDMAC finds the proprietary names Zelapar acceptable from a promotional perspective.		
Denise Toyer, PharmD Deputy Director Division of Medication Errors and Technical Support Office of Drug Safety	Carol Holquist, RPh Director Division of Medication Errors and Technical Support Office of Drug Safety Phone: (301) 827-3242 Fax: (301) 443-9664	

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: July 18, 2005
NDA# 21-479
NAME OF DRUG: **Zelapar** (Selegiline Hydrochloride)
Orally Disintegrating Tablets, 1.25 mg
NDA HOLDER: **Elan 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 Neuropharmacological Drug Products (HFD-120) for a final assessment of the proposed proprietary name, Zelapar. The container labels, carton and insert labeling were reviewed for possible interventions to minimize medication errors.

This proposed name as well as container label, carton labeling, and package insert labeling were first reviewed by DMETS (see ODS consult 04-0065, July 2002). This name was found acceptable and multiple recommendations for changes to the labels and labeling were provided. The container label and carton labeling were again reviewed and recommendations were provided in a consult dated July 2003 (ODS consult number 04-0065-1).

PRODUCT INFORMATION

"Zelapar" contains the active ingredient selegiline hydrochloride. The sponsor is seeking approval for an adjunctive treatment for the management of symptoms in patients with Parkinson's disease being treated with levodopa/carbidopa. Zelapar is available as a 1.25 mg selegiline hydrochloride orally disintegrating tablet. Clinical benefit was observed after one week of 1.25 mg per day therapy, but additional benefits were seen at 2.5 mg daily. Doses above 2.5 mg are not recommended as they have not been studied and have the potential to increase adverse events. The tablet(s) should be taken in the morning before breakfast and without liquid. The tablet(s) will disintegrate in seconds. Patients should avoid ingesting food or liquids 5 minutes before or after taking Zelapar. The tablets are contained in a non-child resistant unit dose blister package (6 pouches of ten tablets each).

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts^{1,2} as well as several FDA databases³ for existing drug names which sound-alike or look-alike to Zelapar 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 conducted⁴. The Saegis⁵ 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.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Zelapar. 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 and 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 Zelapar acceptable from a promotional perspective.
2. The Expert Panel and independent analysis identified seven proprietary names that may be potentially confused with Zelapar. The products are listed in table 1 (see below and page 4), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names for Zelapar Identified by DMETS Expert Panel and Independent Review

Product Name	Established name, Dosage Form(s), Strength(s)	Usual adult dose	Other
Zelapar	Selegiline Oral Disintegrating Tablets, 1.25 mg	1.25 mg to 2.5 mg daily	
Lidopen	Lidocaine HCl 10% Injection (300 mg/3 mL)	Auto-Injector for self administration to the deltoid or anterolateral aspect of thigh.	LA
Relafen	Nabumetone Tablets, 500 mg and 750 mg	1000 mg daily, up to 1500 or 2000 mg daily.	LA
			LA/SA
Sensipar	Cinacalcet HCl Tablets 30 mg, 60 mg, 90 mg	Parathyroid carcinoma: 30 mg twice daily. Titrate the dosage every 2 to 4 weeks through sequential doses of 30 mg twice daily, 60 mg twice daily, 90 mg twice daily, and 90 mg 3 or 4 times/day to normalize serum calcium levels. Secondary HPT: 30 mg once daily. Titrate no more frequently than every 2 to 4 weeks through sequential doses of	LA/SA

b(4)

¹ MICROMEDEX Integrated Index, 2005 MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

³ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-05 Drugs@fda.gov, and the electronic online version of the FDA Orange Book.

⁴ WWW location <http://www.uspto.gov/tmdb/index.html>.

⁵ Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

Product Name	Established name, Dosage Form(s), Strength(s)	Usual adult dose*	Other**
Zelapar	Selegiline Oral Disintegrating Tablets, 1.25 mg	1.25 mg to 2.5 mg daily	
		60, 90, 120, and 180 mg once daily to target goal.	
Teladar	Betamethasone Dipropionate 0.05% Cream, 15 and 45 grams	Apply sparingly to affected areas 2 to 4 times daily	LA/SA
Zanosar	Streptozocin Powder for Injection, 1 gram vials	500 mg/m ² daily for five consecutive days every six weeks until maximum benefit or until treatment-limiting toxicity is observed.	LA/SA
Zenapax	Daclizumab 25 mg/5 mL (Single Use Vials, Refrigerated)	1 mg/kg IV over 15 minutes. Standard course is 5 doses with the first dose no more than 24 hours before transplantation and the four remaining doses at intervals of 14 days.	LA
<p>*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike) *** Name pending approval. Not FOI releasable.</p>			

B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to Zelapar were discussed by the Expert Panel (EPD).

C. PRESCRIPTION ANALYSIS STUDIES

Prescription studies were not repeated since they were conducted during the initial proprietary name review in July 2002 (ODS consult number 04-0065).

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Zelapar, the primary concerns related to look-alike and sound-alike confusion with Lidopen, Relafar, Sensipar, Teladar, Zanosar and Zenapax. DMETS would like to acknowledge that a search found one look-alike medication marketed in another country, Zilopur in Brazil. Although the look-alike characteristics are obvious, DMETS believes the actual possibility for confusion with this product name to be minimal due to the area of marketing. Zelapar is currently marketed in the United Kingdom, Italy and Portugal by Zeneus Pharma. Elan pharmaceuticals have entered a licensing agreement (marketing authorization approval) with Zeneus for US marketing.

b(4)

1. Lidopen may look similar to Zelapar when scripted. Lidopen contains lidocaine in an auto-injector for the acute management of ventricular arrhythmias. Lidopen is available as a 10 % injection (300 mg/3 mL) for delivery into the deltoid muscle or anterolateral aspect of the thigh. The orthographic similarities stem from the shared "p", similarity of the leading "L" and "Z" when written in upper case and the similarly placed upstroke of the "d" and "l."



*** This is proprietary and confidential information that should not be released to the public.

Currently, this drug product may only be ordered by the military services, homeland security and foreign nations. However, DMETS will review this proprietary name in light that the information about the product is readily accessible in standard references. The products share single strength status. Single strength status means that an order may be completed accurately without any indication of strength. However, the drug products differ in frequency (when needed compared to daily) and route of administration (intramuscular compared to sublingually). Thus, the inclusion of these data on an order would serve to differentiate the two drug products. In light of the current distribution method, DMETS believes the possibility for confusion to be minimal.

2. Relafen may look similar to Zelapar when scripted. Relafen contains nabumetone as 500 mg and 750 mg tablets. Nabumetone is indicated for the treatment of osteoarthritis and rheumatoid arthritis. Recommended dosing is 1,000 mg daily up to 2,000 mg daily. The orthographic similarities stem from similarity of the leading "z" and "r", shared "el", shared downstroke with identical placement ("p" and "f") and the similarity of the concluding "ar" and "en", which may be intensified by the tendency to taper concluding letters.

*Zelapar
relafen*

The two drug products share the characteristics of dosage form (tablet), route of administration (oral) and dosing frequency (daily). Although both products are tablets, Zelapar is an oral disintegrating tablet, which is distinct in the administration of the tablet, but may not be a significant difference between the two products. However, they differ in the key characteristic of strength (500 mg and 750 mg compared to 1.25 mg). Due to the differing strengths, DMETS believes the possibility for confusion to be minimal.

3. _____ may look and sound similar to Zelapar when scripted and spoken. _____ is the proposed name _____ for _____ strengths _____

b(4)

_____ The orthographic similarities stem from the possibility for the leading "S" and "Z" to appear similar and the shared concluding "par". However, the upstroke of the "i" in Zelapar compared to the "n" of _____ should distinguish the two upon scripting. The phonetic similarities stem from the shared three syllables and concluding "apar" for both as the "i" in _____ will commonly be pronounced as a "ä" sound. However, the leading "san" and "zel" should distinguish the two in speech.

b(4)

b(4)

Zelapar

b(4)

The products share the overlapping characteristics of route of administration (oral) and frequency of dosing (daily). However, they differ in the key characteristic of strength since _____ compared to the single 1.25 mg strength of Zelapar. Due to the weak orthographic and phonetic similarities and the differing product strengths, DMETS believes the possibility for confusion to be minimal.

b(4)

4. Sensipar may look and sound like Zelapar when scripted and spoken. Sensipar contains cinacalcet in 30 mg, 60 mg and 90 mg tablets for the treatment of hypercalcemia in patients

*** This is proprietary and confidential information that should not be released to the public.

with parathyroid carcinoma and secondary hyperparathyroidism in patients with chronic kidney disease on dialysis. Recommended initial dosing is 30 mg twice daily. For carcinoma patients, the dose is titrated every two to four weeks through sequential doses of 30 mg twice daily, 60 mg twice daily, 90 mg twice daily, and 90 mg, three to four times per day to normalize serum calcium levels. For hyperparathyroidism, the dose may be titrated at sequential doses of 60, 90, 120, and 180 mg once daily to target goal depending on laboratory values taken every 2 to 4 weeks. The orthographic similarities stem from the shared "par" and possibility for the leading "Se" to resemble "Ze." However, the upstroke of the "l" in Zelapar should help distinguish between the two names. The phonetic similarities stem from the shared three syllable count and concluding "par." However, the leading "Sens" and "Zela" should distinguish the two in speech.

Zelapar

Sensapar

The two drug products share a similar dosage form (tablets) and route of administration (oral). However they differ in many characteristics that include frequency of dosing (twice daily compared to daily), indication (hypercalcemia/hyperparathyroidism compared to Parkinson's), and strength (30 mg, 60 mg and 90 mg compared to 1.25 mg). Due to these differences and the lack of convincing look-alike and sound-alike potential, DMETS believes the possibility for confusion to be minimal.

5. Teladar may look and sound like Zelapar when scripted. Teladar contains 0.05% betamethasone dipropionate cream in 15 gram and 45 grams tubes for the relief of inflammatory and pruritic manifestations of dermatoses. Recommended dosing is to apply sparingly to affected areas 2 to 4 times daily. The orthographic similarities stem from the resemblance of the leading, lower case "t" and upper case "Z", shared central "ela" and concluding "ar." However, the upstroke of the "d" in Teladar should be distinguishable from the downstroke of "p" of Zelapar. The phonetic similarities stem from the shared "ela" and concluding "ar"; however, the leading "T" and "Z" should help to distinguish the two in speech.

Teladar

Zelapar

The products share single strength status and can have the directions of "use as directed"/"UD." Single strength status means that an order may be completed accurately without any indication of strength. Orders for both drug products should indicate the dispensing amount for both Teladar and Zelapar, but particularly Zelapar. In addition, the products differ in route of administration (topical compared to oral), dosing frequency (two to four times daily compared to daily) and dosage form (cream compared to oral disintegrating tablet). Although this drug product is only available in a cream dosage form, practitioners will not likely be aware of this as betamethasone is an older medication and known to be available in multiple dosage forms (i.e cream, ointment, lotion and aerosol); thus, it is credible to believe that dosage form will be indicated on the prescription order. Another key factor appears to be the lack of availability in the marketplace. In common references (e.g. Facts and Comparisons), Teladar is listed; however, upon searching the 2005 Edition of the Redbook and popular websites such as Destination Rx, Walgreens and CVS, the product does not appear available. Due to poor orthographic and phonetic similarities, differing dosage forms, dispensing amounts and apparent lack of availability in the marketplace, DMETS believes the possibility for confusion to be minimal.

6. Zanosar may look and sound similar to Zelapar when scripted and spoken. Zanosar contains streptozocin for the treatment of metastatic islet cell carcinoma of the pancreas.

Zanosar is available as 1 gram injectable vials with recommended dosing of 500 mg/m² for five consecutive days every six weeks until maximum benefit or until treatment-limiting toxicity is observed. The orthographic and phonetic similarities stem from the shared leading "Z" and concluding "ar". Orthographically, the up and downstrokes of Zelapar should differentiate the two upon scripting. Phonetically, both names are three syllables, but the "ano" and "ela" should distinguish the two in speech.

Zanosar
Zelapar

The drug products differ in the most pertinent product characteristics for order completion such as strength (1 gram compared to 1.25 mg), route of administration (intravenous compared to oral), dosage form (powder for injection compared to tablets), and dosing (500 mg/m² compared to 1.25 to 2.5 mg daily). There is a limited possibility for dose overlap at 1.25 grams for Zanosar and 1.25 mg of Zelapar, which would occur in a 270 pound patient who is 74 inches tall, which is a rather large patient. In addition, both products could be considered to be dosed daily (daily infusion for five days every six weeks compared to daily). Thus the likelihood that most chemotherapy orders will document the following: dose or dosing regimen, frequency, and route of administration with the potential for weight/height (body surface area) and next scheduled infusion date should help to alleviate confusion. In addition, most institutions have protocols for multiple practitioner review of oncology medications due to potential toxicity; this providing another method to limit error. Furthermore, Zanosar should be administered under the supervision of a physician, usually by an experienced nurse, in clinics or wards that specialize in oncology/chemotherapy; thus, providing another method of differentiation as the practitioners will be familiar with the ordered product. Although some limited dose and frequency overlap may occur, the context of use, differing products characteristics and poor look and sound-alike similarities should help to minimize the potential for name confusion between these two products.

7. Zenapax may look similar to Zelapar when scripted. Zenapax contains daclizumab in a 25 mg/5 mL single use vial for the prophylaxis of acute organ rejection in patients receiving renal transplants. Zenapax is used in conjunction with cyclosporine and corticosteroids. Recommended dosing is 1 mg/kg to be mixed with 50 mL of sterile 0.9% sodium chloride solution and administered via a peripheral or central vein over a fifteen minute period of time. The regimen is five doses, the first to be given no more than 24 hours before transplantation with the four remaining doses to be given at fourteen day intervals. The orthographic similarities stem from the shared leading "Z" and concluding "apa." However, the upstroke of the "L" should help to differentiate the two upon scripting.

Zenapax
Zelapar

The potential for confusion could exist in an overlap in dosing, if the decimal is overlooked. For example, Zelapar is typically dosed at 1.25 mg and 2.5 mg, which could be confused with Zelapar 125 mg (125 kg patient) or 25 mg (25 kg pediatric patient). However, the dosing intervals differ as Zenapax is dosed as five doses with one given no more than 24 hours before transplantation and the remaining four administered at fourteen day intervals, which differs from the daily dosing of Zelapar. In addition, Zenapax will be used before and just after renal transplantation, the administration will likely occur in an inpatient setting or at clinics associated with the hospital. JCAHO requires that medication orders document all the elements required to accurately complete the order, such as frequency and route of administration. Thus, the inclusion of these data on an order would serve to differentiate the two drug products. The drug products differ in the following characteristics: route of administration (intravenous compared to oral), dosage form (solution for injection

compared to tablets), context of use (in association with inpatient renal transplant compared to primarily outpatient use), and storage (refrigerated compared to room temperature). Due to the differing characteristics and Zenapax context of use, DMETS believes the possibility for confusion to be minimal.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In the review of the proposed labels and labeling for Zelapar, DMETS has identified the following areas of possible improvement, which may minimize potential user error. DMETS has identified several areas of possible improvement, which might minimize potential user error

A. GENERAL COMMENT

The "Storage" section reads ~~_____~~ This statement is confusing since each tablet is individually sealed in a blister unit. Provide additional information for a healthcare professional and patient to understand the significance and reason for this statement. b(4)

B. BLISTER LABELS

1. Assure the established name is at least ½ the size of the proprietary name in accordance with 21 CFR 201.10(g) (2).
2. We encourage the inclusion of the finished dosage form "oral disintegrating tablets" in conjunction with the established name. For example:

(Selegiline HCl) Oral Disintegrating Tablets

3. Please revise the font or coloring scheme of the white lettering on purple background. As currently represented, the smaller font is difficult to read.
4. Consider an addition to the "Pull Here" statement, which would again warn patients not to attempt pushing the tablets through the foil.

C. POUCH LABELING (SACHET)

1. See Comments under A and B.
2. Provide a remark or guidance on how to open the sachet. This is to assure that the patient will not accidentally damage the internal contents.
3. Delete or reduce the prominence of the "Zydis" statement, as the introduction of this name may be confusing to the reader.
4. If the blisters should be stored in the sachet after opening, please add a statement to the labeling.
5. Increase the prominence of the product strength and relocate the strength to appear in conjunction with the proprietary and established names. The current presentation does not properly emphasize this critical information.
6. Referencing "Instructions for use", consider revising bullet #2 to read:

This provides a complete listing of how to take the medication for the patient on packaging that b(4)

may be maintained. This could help to assure proper ingesting of Zelapar.

D. CARTON LABELING (sample and trade unit pouch)

See comments A and B and C-3 and 7.

E. PACKAGE INSERT LABELING

1. DMETS questions what occurs when the tablet is swallowed in lieu of dissolving on the tongue. If swallowing the tablet may result in injury or changes to therapy, please state such in the package insert (possible under Description, Pharmacokinetics, Information for Patients and Dosage and Administration).

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IV. RECOMMENDATIONS:

- A. DMETS has no objections to the use of the proprietary name, Zelapar from a safety perspective. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.
- B. DMETS recommends implementation of the label and labeling revision outlined in section III of this review to minimize potential errors with the use of this product.
- C. DDMAC finds the proprietary names Zelapar 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. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-827-1998.

Kimberly Culley, RPh
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

Alina Mahmud, RPh, MS
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

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/s/

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9/14/2005 11:09:03 AM
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Carol Holquist
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CONSULTATION RESPONSE
Division of Medication Errors and Technical Support
Office of Drug Safety
(DMETS; HFD-420)

DATE RECEIVED: April 10, 2002

DUE DATE: June 28, 2002

ODS CONSULT #: 02-0065

TO: Russell Katz, MD
Director, Division of Neuropharmacological Drug Products
HFD-120

THROUGH: Teresa Wheelous
Senior Regulatory Project Manager
HFD-120

PRODUCT NAME:
Zelapar
(Selegiline Hydrochloride)
Orally Dissolving Tablets
1.25 mg

NDA SPONSOR:
Elan Pharmaceuticals, Inc.

NDA # 21-479

SAFETY EVALUATOR: Scott Dallas, R.Ph.

SUMMARY: In response to a consult from the Division of Neuropharmacological Drug Products (HFD-120), the Division of Medication Errors and Technical Support (DMETS) conducted a review of the proposed proprietary name, "Zelapar", to determine the potential for confusion with approved proprietary and established names as well as pending names.

DMETS RECOMMENDATION: DMETS has no objections to the use of the proprietary name, "Zelapar". In addition, DMETS recommends consulting Dan Boring of the USAN council and the Labeling and Nomenclature Committee for the proper designation of the dosage form. DMETS also recommends implementation of the labeling revisions outlined in section III of this review to minimize potential errors with the use of this product. This name and its associated labels and labeling 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.

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**Division of Medication Errors and Technical Support
Office of Drug Safety
HFD-420; Parklawn Building Room 15B32
Center for Drug Evaluation and Research**

PROPRIETARY NAME REVIEW

DATE OF REVIEW: July 3, 2002

NDA NUMBER: 21-479

NAME OF DRUG: Zelapar
(Selegiline Hydrochloride)
Orally Dissolving Tablets
1.25 mg

NDA SPONSOR: Elan Pharmaceuticals, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Neuropharmacological Drug Products (HFD-120) for an assessment of the proposed proprietary name, Zelapar. This proposed tradename was submitted with NDA 21-479. The container labels, carton and insert labeling were reviewed for possible interventions in minimizing medication errors.

PRODUCT INFORMATION

"Zelapar" contains the active ingredient selegiline hydrochloride. This product is seeking approval for an adjunctive treatment for the management of symptoms in patients with Parkinson's disease that are exhibiting deterioration of their response to levodopa/carbidopa therapy. Zelapar is available as a 1.25 mg selegiline hydrochloride orally dissolving tablet. Doses of 1.25 mg and 2.5 mg selegiline hydrochloride were effective as adjunctive therapy. The tablet(s) should be taken in the morning before breakfast and without liquid. Patients should avoid swallowing for 2 minutes after taking Zelapar. Patients should also avoid ingesting food or liquids 5 minutes before or after taking Zelapar. The tablets are contained in a unit dose blister package with a foil backing.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts^{1,2} as well as several FDA databases³ for existing drug names which sound alike or look alike to "Zelapar" 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 trademark electronic

¹ MICROMEDEX Healthcare Intranet Series, 2002, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes the following published texts: DrugDex, Poisindex, Martindale (Parfitt K (Ed), Martindale: The Complete Drug Reference. London: Pharmaceutical Press. Electronic version.), Index Nominum, and PDR/Physician's Desk Reference (Medical Economics Company Inc, 2002).

² Facts and Comparisons, 2002, Facts and Comparisons, St. Louis, MO.

³ The Drug Product Reference File [DPR], Established Evaluation System [EES], the DMETS database of proprietary name consultation requests, New Drug Approvals 98-02, and the electronic online version of the FDA Orange Book.

search system (TESS) was conducted⁴. The Saegis⁵ 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 prescription analysis studies, 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.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name "Zelapar". Potential concerns regarding drug marketing and promotion related to the proposed names were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and 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.

The Expert Panel identified three proprietary and or established names that were thought to have the potential for confusion with "Zelapar". These products are listed in Table 1, along with the dosage forms available and usual dosage.

DDMAC did not have any concerns with the promotional aspects of the name "Zelapar".

TABLE 1

Product Name	Generic name, Dosage form(s)	Usual adult dose	Other
Zelapar	Serentina, 5 mg ovalloids Orally Disintegrating Tablets 25 mg	Treatment of Parkinson's disease: Place 1 or 2 tablets on top of tongue and allow to dissolve. The tablets should be taken in the morning, before breakfast, and without liquid.	
Sonata	Zaleplon, Capsules, 5 mg and 10 mg	Treatment of Insomnia: Take one 10 mg capsule orally immediately before bedtime.	S/A and L/A per DMETS
Zemplar	Paricalcitol, Injection, 5 mcg/mL in 1 mL and 2 mL single dose vials.	Treatment of secondary hyperthyroidism: Inject 0.04 mcg/kg to 0.1 mcg/kg as an intravenous bolus every other day during dialysis.	S/A and L/A per DMETS
Zinecard	Dexrazoxane, Powder for Injection, lyophilized 250 mg and 500 mg vials	Reduction of cardiomyopathy associated with doxorubicin administration: Administer less than 30 minutes before the doxorubicin injection. The recommended dosage ratio of dexrazoxane:doxorubicin is 10:1.	S/A per DMETS
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

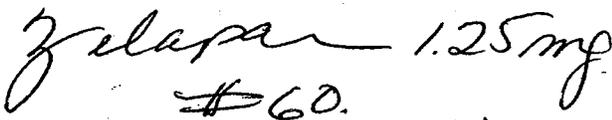
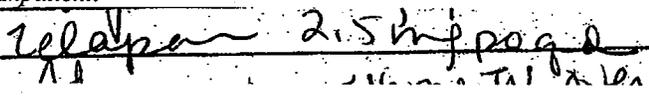
⁴WWW location <http://tess.uspto.gov/bin/gate.exe?f=tess&state=k0n826.1.1>

⁵Data provided by Thomson & Thomson's SAEGIS(tm) Online Service, available at www.thomson-thomson.com.

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology

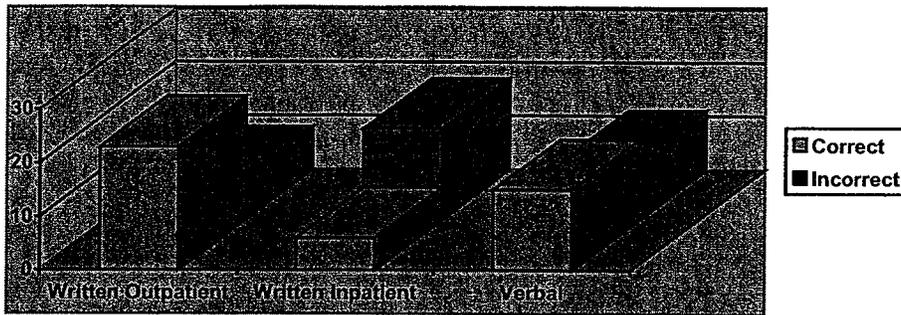
Three separate studies were conducted within FDA for the proposed proprietary name to determine the degree of confusion of Zelapar with other U.S. drug names due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 110 health care professionals (nurses, pharmacists, and physicians). This exercise was conducted in an attempt to simulate the prescription ordering process. A DMETS staff member wrote an inpatient order and outpatient prescriptions, each consisting of a combination of marketed and unapproved drug products and prescriptions for Zelapar. These written prescriptions were optically scanned and one prescription was delivered via email to each study participant. In addition, one DMETS staff member recorded a verbal outpatient prescription that was then delivered to a group of study participants via telephone voicemail. Each reviewer was then requested to provide an interpretation of the prescription via email.

HANDWRITTEN PRESCRIPTIONS	VERBAL PRESCRIPTION
<p><i>Outpatient:</i></p> 	<p><i>Outpatient:</i></p> <p>Zelapar Dispense 60 Directions 2 tablets once a day as directed</p>
<p><i>Inpatient:</i></p> 	

2. Results

Results of the Zelapar exercises are summarized below:

Study	No. of participants	# of responses (%)	Zelapar response	Other response
<i>Written Outpatient</i>	39	31 (79%)	23 (74%)	8 (26%)
<i>Inpatient</i>	33	23 (70%)	6 (26%)	17 (74%)
<i>Verbal Outpatient</i>	38	26 (68%)	15 (58%)	11 (42%)
Total	110	80 (73%)	44 (55%)	36 (45%)



Among participants in the written outpatient prescription study, 23 of 31 respondents (74%) interpreted the name correctly. Incorrect interpretations included Zelapan (6), Zelapa (1), and Zelopar (1).

Among participants in the written inpatient prescription study, 6 of 23 respondents (26%) interpreted the name correctly. Incorrect interpretations included Zelapan (11), Zelapam (2), Zelepen (1), Zelopan (1), Aelzepam (1), and Zelepen (1).

Among participants in the verbal outpatient prescription study, 15 of 26 respondents (58%) interpreted the name correctly. Incorrect interpretations included Zelopar (4), Zelpar (1), Zalapram(1), Zelepar (1), Zellapar (1), Zilapar (1), Zalopar (1) and Zelapan (1).

None of the misinterpreted names is a currently marketed drug product.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name, "Zelapar", the primary concerns raised by the DMETS expert panel was related to sound alike and/or look alike names that already exist in the US marketplace. The products considered having the greatest potential for confusion with "Zelapar" were Zaleplon, Zemplar and Zinecard.

Zaleplon is the established name for Sonata. Zaleplon is indicated for the short-term management of insomnia. Zaleplon is available as a 5 mg and 10 mg capsule. The usual dose for nonelderly adults is a 10 mg capsule immediately before bedtime. For elderly and low weight individuals the recommended dose is a 5 mg capsule immediately before bedtime. Zaleplon and Zelapar have the potential to sound similar when spoken and look similar when scripted. When spoken the first five letters can sound very similar depending on how well the vowels "a" and "e" are enunciated. Both names also consist of 3 syllables, which causes a similar rhyming quality. When scripted the first five letters of each name, "Zalep" and "Zelap" can look similar. The last two trailing letters of each name, "ar" and "on" can also look similar when scripted. Different characteristics of the names are the sound of the last syllable, "plon" or "par" when spoken, and the letter "l" is unique in the last syllable of Zaleplon when scripted. Zaleplon and Zelapar have different product strengths (5 mg or 10 mg vs. 1.25 mg), package configurations (bottles vs. blister pack), indications for use (insomnia vs. Parkinson disease), usual dose (10 mg vs. 1.25 mg or 2.5 mg), time of administration (bedtime vs. before breakfast), and dosage form (capsule vs. dissolving tablet). Zaleplon and Zelapar could potentially be stored in close proximity to each other on a pharmacy shelf. However, Zaleplon is classified as a controlled scheduled IV

medication and could possibly be stored in a locked pharmacy safe. Zaleplon is available in two strengths, which would cause all Zaleplon prescriptions to include the product strength. Zelapar has specific directions that must be communicated to the patient. The prescribing physician should educate the patient and possibly even a family member that the medication should be taken in the morning before breakfast and without liquid. The ingestion of food and liquid should be avoided 5 minutes before and after taking the medication. This will provide time for the tablet to dissolve and be absorbed. A patient with Parkinson disease may have normal mental ability, but impaired physical ability. Therefore, a family member may need to be educated to assist in opening the blister packing of the tablets. Zelapar should be administered on a daily basis, while Zaleplon could be administered on a "prn" or as needed basis. Both medications could have directions of "ud" or "as directed." Although, a Zaleplon prescription may commonly include the phrase "for sleep", for example: prn for sleep or ud for sleep. A Zelapar prescription should include the number of tablets to be administered and may possibly include some of the instructional information previously mentioned, for example: "before breakfast". These differences in administration would also cause the prescription directions to differentiate between the products if the prescription is not written with only "as directed". Although it is possible for the names to look alike or sound alike, the risk of dispensing the wrong medication is low based on the differences between the medications.

Zemplar is the proprietary name for paricalcitol. Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure. Zemplar is available as a 5 mcg/mL injection in 1 mL and 2 mL single dose vials. The initial recommended dose is 0.04 mcg/kg to 0.1 mcg/kg administered as a bolus dose no more frequently than every other day. Zemplar and Zelapar have the potential to sound similar when spoken and look similar when scripted. The first two letters and last two letters of each name are exactly the same. When spoken these characteristics cause the names to sound similar. As stated above both names begin and end with the same letters. Both names also contain 7 letters, which causes the names to have a similar length. When scripted these characteristics cause the names to look similar. Zemplar contains 2 syllables and Zelapar contains 3 syllables, which causes the names to have a different rhyming quality when spoken. The letter "l" is common to both names, but is located in different syllables, which can aid in differentiating the names when scripted. Zemplar and Zelapar have different product strengths (5 mcg/mL vs. 1.25 mg), indication for use (hyperparathyroidism associated with chronic renal failure vs. Parkinson Disease), usual dose (0.04 mcg/kg to 0.1 mcg/kg vs. 1.25 mg or 2.5 mg), dosage form (injection vs. tablets), route of administration (intravenous vs. oral) and frequency of administration (every other day vs. daily). These medications would probably be stored in different locations within a pharmacy based on their route of administration. Each prescription of Zemplar would require a dose individualized for each patient. Zemplar would generally only be available in a clinic or hospital setting, where patient can be monitored. Zemplar is not a medication dispensed at a retail pharmacy. Although it is possible for the names to look alike or sound alike, the risk of dispensing the wrong medication is low based on the differences between the medications.

Zinecard is the proprietary name for dexrazoxane. Zinecard is specifically indicated for the reduction of the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer. These patients should have received a cumulative dose of 300 mg/m² of doxorubicin and who would benefit from continuing therapy with doxorubicin. Zinecard is available as an injection and the recommended dosage ratio of dexrazoxane:doxorubicin is 10:1. Zinecard and Zelapar have the potential to sound alike when spoken. The "Zi" and "Ze" can sound similar along with "card" and "par" if the "d" is not clearly enunciated. Both names contain 3 syllables, which causes the names to have a rhyming quality. Zinecard and Zelapar have different product strengths (250 mg and 500 mg/vial vs. 1.25 mg), indication for use (reduction of cardiomyopathy associated with doxorubicin vs. Parkinson Disease), usual dose (10:1 ratio of dexrazoxane:doxorubicin vs. 1.25 mg or 2.5 mg), dosage form (injection vs. tablets), route of administration (intravenous vs. oral) and frequency of administration (during a chemotherapy cycle vs. daily). These medications would probably be stored in different locations within a pharmacy based on their route of administration. Each prescription of Zinecard would require a dose individualized for each patient. All Zinecard prescriptions would require the dose to be checked against the dose of doxorubicin to verify the proper dosing ratio of 10:1. Zinecard would generally only be available in a clinic or hospital setting. Zinecard is not a medication dispensed at a retail pharmacy. Although it is possible for the names to sound alike, the risk of dispensing the wrong medication is low based on the differences between the medications.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

DMETS has reviewed the container label, carton labeling, and package insert labeling in an attempt to focus on safety issues to prevent possible medication errors. We have identified areas of improvement, in the interest of minimizing potential user error and patient safety.

DMETS recommends consulting Dan Boring of the USAN council and the Labeling and Nomenclature Committee for the proper designation of the dosage form. The sponsor has labeled their product as an "Orally Dissolving Tablet". DMETS questions whether the designation of "Orally Disintegrating Tablet" may be more appropriate for this dosage form.

A. Container Label (foil blister packaging)

1. Increase the prominence of the proprietary and established names.
2. Prominently include the product strength in direct association with the proprietary and established names.
3. Decrease the prominence of the company name/logo.

B. Carton Labeling (pouch sample packaging)

1. See comment A2 and A3.
2. Increase the prominence of the established name.
3. Relocate the "Each Zelapar tablet contains 1.25 mg selegiline hydrochloride in a Zydys fast-dissolving formulation" statement to the side panel.

IV. RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, "Zelapar".
2. DMETS recommends consulting Dan Boring of the USAN council and the Labeling and Nomenclature Committee for the proper designation of the dosage form.
3. DMETS recommends the above labeling revisions to encourage the safest possible use of the product.

DMETS would appreciate feedback of the final outcome of this consult. We are willing to meet with the Division for further discussion as well. If you have any questions concerning this review, please contact Sammie Beam at 301-827-3242.

Scott Dallas, R.Ph.
Safety Evaluator
Office of Drug Safety (DMETS)

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Carol Holquist
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Jerry Phillips
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