CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-813

PROPRIETARY NAME REVIEW(S)

NDA 21-813

5S

Elestrin™ (estradiol gel)

BioSante Pharmaceuticals Inc.

PM: George Lyght

DDMAC RECOMMENDATIONS
See DMETS Review page 1

"Acceptable from a promotional perspective"

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO22, M/S 4447)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**OSE REVIEW #:** 06-0015
April 14, 2006	July 12, 2006	
DOCUMENT DATE: February 16, 2006 and August 9, 2006	**PDUFA DATE:** December 16, 2006	

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

THROUGH: Linda Kim-Jung, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

FROM: Laura Pincock, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME: **Bio-E-Gel™**
(Transdermal Estradiol Gel)
0.06%

NDA#: 21-813

NDA SPONSOR: Bio Sante Pharmaceuticals Inc.

RECOMMENDATIONS:

1. DMETS did not identify any look-alike or sound-alike name concerns with the proposed proprietary name, Bio-E-Gel.

Redacted 10 page(s)

of trade secret and/or

confidential commercial

information from

Proprietary Name Review

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

/s/

Laura Pincock
9/13/2006 09:40:22 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
9/13/2006 10:12:38 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
9/13/2006 11:09:52 AM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO22, Rm. 4447)

DATE RECEIVED: November 13, 2006 **DOCUMENT DATE:** February 16, 2006	**DESIRED COMPLETION DATE:** December 12, 2006	**OSE REVIEW #:** 2006-808

TO: Scott Monroe, MD
Acting Director, Division of Reproductive & Urologic Products
HFD-580

THROUGH: Alina R. 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: Tina M. Tezky, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: **Elestrin™** Estradiol) Gel 0.06% **NDA#:** 21-813	**NDA SPONSOR:** BioSante Pharmaceuticals, Inc.

RECOMMENDATIONS:

1. DMETS has no objection to the use of the proprietary name, Elestrin™. 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. Revised container labels, carton and insert labeling were not submitted for review and comment. We refer you to the label and labeling comments contained in DMETS review 06-0015 dated May 8, 2006.

3. DDMAC finds the proprietary name, Elestrin™, 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 Cherye Milburn, Project Manager, at 301-796-2084.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
HFD-420; WO22, Rm. 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: November 28, 2006

NDA#: 21-813

NAME OF DRUG: **Elestrin™**
(Estradiol) Gel
0.06%

NDA HOLDER: BioSante Pharmaceuticals, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Reproductive and Urologic Products (HFD-580) for a review of the proprietary name, "Elestrin™", regarding potential name confusion with other proprietary and/or established drug names. This NDA was reviewed by DMETS for the tradename "Bio-E-Gel". Although DMETS did not identify any look-alike or sound-alike name concerns, [redacted] The sponsor has submitted the proposed proprietary name "Elestrin" for review and comment. Revised container labels, cartons, and insert labeling were not submitted for review and comment at this time.

PRODUCT INFORMATION
Elestrin (estradiol) gel is being developed as a topical estrogen product for the treatment of moderate-to-severe vasomotor symptoms associated with menopause [redacted] When estrogen is prescribed for a postmenopausal woman with a uterus, a progestin should also be initiated to reduce the risk of endometrial cancer.

Elestrin is proposed to be packaged in a [redacted] pump container containing 144 gram of gel, which delivers 100 metered doses. Each metered actuation delivers 0.87 grams of Elestrin. Patients should be started at the lowest effective dose which is 0.87 grams daily. The recommended dose is to use 1 (0.87 gram), 2 (1.7 gram)[redacted] actuations once daily, applied to the upper arm area, spreading the gel by gently rubbing over the upper arm and shoulder area.

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 Elestrin 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[5]. The SAEGIS™ Online service [6] 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 Elestrin. 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 did not have concerns with the name, Elestrin, in regard to promotional claims.

2. The Expert Panel identified eighteen proprietary names that were thought to have the potential for confusion with Elestrin. Two additional names, Alustra, and Elimite, were identified through independent analysis. These products are listed in Table 1, along with the dosage forms available and usual dosage (see pages 4 & 5).

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[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, Missouri.

[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.

[4] Phonetic and Orthographic Computer Analysis (POCA).

[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

Table 1: Potential Sound-Alike/Look-Alike Names Identified for Elestrin

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Elestrin	Estradiol Gel 0.06% (0.87 grams/actuation)	1 [ ] actuations (0.87 [ ] grams) once daily applied to the upper arm using a metered-dose pump.	
Alustra Rx	Hydroquinone Cream 4%	Apply to affected area twice daily.	LA/SA
Elimite Rx	Permethrin Cream 5%	Apply from head to toe, leave on for 8 – 14 hours, wash off. May repeat in 14 days if necessary.	LA
Elestat Rx	Epinastine Ophthalmic Solution 0.05%	Instill one drop into each eye twice daily.	LA/SA
Eloxatin Rx	Oxaliplatin Injection 50 mg, 100 mg	65 mg/m^2 – 85 mg/m^2 in combination with other antineoplastic agents, every two weeks for 12 cycles.	LA
Celontin Rx	Methsuximide Capsules 150 mg, 300 mg	300 mg – 1200 mg PO daily, based on individual patient response.	LA
Celestone Rx	Betamethasone Oral Solution, USP 0.6 mg/5 mL *Betamethasone Topical Cream (Disc.)* *2%* *Betamethasone Tablets (Disc.)* *0.6 mg* *Betamethasone Injection (Disc.)* *3 mg base/mL*	0.6 mg – 7.2 mg PO per day, depending on specific disease being treated.	LA
Elmiron Rx	Pentosan Polysulfate Sodium Capsules 100 mg	100 mg PO three times a day.	LA
Leustatin Rx	Cladribine Injection 10 mg/10 mL	0.09 mg/kg/daily administered by intravenous infusion continuously over 7 consecutive days.	LA
Relpax Rx	**Eletriptan** Tablets 20 mg, 40 mg	20 mg – 40 mg as a single oral dose at the onset of migraine. May repeat after 2 hours if symptoms continue.	LA
Questran Rx	Cholestyramine Powder for Oral Suspension 4 grams *Cholestyramine Tablets (Disc.)* *800 mg, 1 gram*	1 – 2 packets (4 – 8 grams) once or twice a day.	LA
Estring Rx	Estradiol Vaginal Ring 2 mg	Insert vaginally and leave in place for 90 days, if continuation of therapy is deemed appropriate, replace with new vaginal ring.	SA
Loestrin 21 1/20 Rx Loestrin 21 1.5/30 Rx Loestrin 24 FE Rx Loestrin FE 1/20 Rx Loestrin FE 1.5/30 Rx	Norethindrone/Ethinyl Estradiol Tablets 1 mg/20 mcg Norethindrone/Ethinyl Estradiol Tablets 1.5 mg/30 mcg Norethindrone/Ethinyl Estradiol Tablets 1 mg/20 mcg Norethindrone/Ethinyl Estradiol Tablets 1 mg/20 mcg Norethindrone/Ethinyl Estradiol Tablets 1.5 mg/30 mcg	One tablet PO daily.	LA/SA
Norlestrin 21 1/50 *Discontinued* Norlestrin 21 2.5/50 *Discontinued* Norlestrin 28 1/50 *Discontinued* Norlestrin FE 1/50 *Discontinued* Norlestrin FE 2.5/50 *Discontinued*	Norethindrone/Ethinyl Estradiol Tablets 1 mg/50 mcg Norethindrone/Ethinyl Estradiol Tablets 2.5 mg/50 mcg Norethindrone/Ethinyl Estradiol Tablets 1 mg/50 mcg Norethindrone/Ethinyl Estradiol Tablets 1 mg/50 mcg Norethindrone/Ethinyl Estradiol Tablets 2.5 mg/50 mcg	One tablet PO daily.	LA/SA
Xenical Rx	**Orlistat** Capsules 120 mg	120 mg three PO times a day, with each fat containing meal.	LA

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Elestrin	Estradiol Gel 0.06% (0.87 grams/actuation)	1 [ ] actuations (0.87 [ ] grams) once daily applied to the upper arm using a metered-dose pump.	
Elaprin*** [ ] IND 69,863	Heparin/[ ] Capsules [ ]	[ ]	SA
Lecithin *supplement*	Lecithin Capsules Lecithin Liquid Lecithin Granules	Because lecithin is not considered an essential nutrient, currently, no Recommended Daily Allowance (RDA) has been set.	LA
Olean *food additive*	**Olestra**	Artificial fat substance.	LA/SA
Elastin	Elastin	Elastin is a protein in connective tissue that is elastic and allows many tissues in the body to resume their shape after stretching or contracting. Elastin helps skin to return to its original position.	LA/SA
Elipten *chemical*	3-(4-aminophenyl)-3-ethyl-piperidine-2,6-dione	Not applicable.	LA
Oletetrin *chemical*	2-(amino-hydroxy-methylidene)-4-dimethylamino-6,10,11,12a-tetrahydroxy -6-methyl-4,4a,5,5a-tetrahydrotetracene-1,3,12-trione	Not applicable.	LA

*Frequently used, not all-inclusive.
**LA (look-alike), SA (sound-alike)
***[ ]

B. PRESCRIPTION STUDY ANALYSIS

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Elestrin 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 122 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Elestrin (see page 6). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Elestrin #1 Apply to upper arm once a day.	Elestrin #1 Apply to upper arm once a day.
Inpatient RX: Elestrin Apply to upper arm once a day	

3. Results:

One respondent from the verbal prescription study interpreted the proposed name as "Alastra" and another interpreted the proposed name as "Alestra", which both look and sound like the proprietary name Alustra. The ~~remainder~~ of misinterpretations were misspelled/ phonetic variations of the proposed name, Elestrin. See Appendix A for the complete listing of interpretations from the verbal and written studies.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Elestrin, the primary concerns relating to look-alike and sound-alike confusion with Elestrin are Eloxatin, Elestat, Celontin, Celestone, Elipten, Elmiron, Leustatin, Eletriptan, Lecithin, Questran, Oletetrin, Estring, Loestrin, Elaprin***, Elastin, Olestra, Norlestrin, Orlistat, Alustra, and Elimite.

Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that Elestrin could be confused with any currently marketed U.S. prescription products. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations, primarily due to sample size. One respondent from the verbal prescription study interpreted the proposed name as "Alastra" and another interpreted the proposed name as "Alestra", which both look and sound like the proprietary name Alustra. The remainder of misinterpretations were misspelled/ phonetic variations of the proposed name, Elestrin.

Upon initial analysis of the names Elipten, Leustatin, Eletriptan, Lecithin, Questran, Oletetrin, Loestrin, Elastin, Olestra, Norlestrin, and Orlistat; these names were not reviewed further for the following reasons:

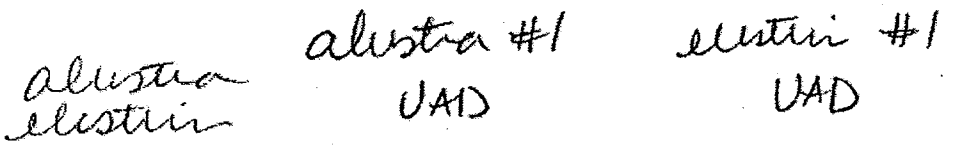
- Elipten was not reviewed further because it is a chemical and will not be used in a prescribing or patient care setting.
- Leustatin was not reviewed further due to lack of convincing look-alike similarities with Elestrin, in addition to numerous differing product characteristics such as dosage form, route of administration, available strength, usual dose, frequency of administration, and setting for use.
- Eletriptan was not reviewed due to lack of convincing look-alike similarities with Elestrin, in addition to numerous differing product characteristics such as dosage form, route of administration, available strength, usual dose, and frequency of administration.
- Lecithin was not reviewed due to lack of convincing look-alike similarities with Elestrin, in addition to the fact that it is a supplemental nutrient with differing product characteristics such as dosage form and route of administration.
- Questran was not reviewed due to lack of convincing look-alike similarities with Elestrin, in addition to numerous differing product characteristics such as dosage form, route of administration, available strength, usual dose, and frequency of administration.
- Oletetrin is a chemical and will not be used in a prescribing or patient care setting.
- Loestrin is an oral contraceptive product line that is currently available with five different modifiers (Loestrin 21 1/20, Loestrin 21 1.5/30, Loestrin 24, Loestrin FE 1/20, and Loestrin FE 1.5/30). In addition, differing product characteristics such as dosage form and route of administration will help distinguish these products from Elestrin.
- Elastin is a protein and will not be used in a prescribing or patient care setting.
- Olestra was not reviewed further because it is a food additive and is unlikely to be used in a prescribing or patient care setting.
- Norlestrin is a discontinued oral contraceptive product line that was available with five different modifiers (Norlestrin 21 1/50, Norlestrin 21 2.5/50, Norlestrin 28 1/50, Norlestrin FE 1/50, and Norlestrin FE 2.5/50). Generic versions of these products are not currently available.
- Orlistat was not reviewed further due to lack of convincing look-alike similarities with Elestrin, in addition to numerous differing product characteristics such as dosage form, route of administration, available strength, usual dose, and frequency of administration.

The remaining names of concern (Alustra, Elimite, Elestat, Eloxatin, Celontin, Celestone, Elmiron, Estring, and Elaprin***) are discussed in detail below.

1. Alustra was identified as having look-alike and sound-alike similarities with the proposed name, Elestrin.

   Alustra (hydroquinone) is a skin bleaching agent used to treat freckles, age spots, and other skin discolorations. Alustra was available as a 4% topical cream, packaged in [redacted], and the usual dose is to apply to the affected area twice daily.

The names Alustra and Elestrin have four overlapping letters in the same position (ALUSTRA vs. ELESTRIN), which gives the names orthographic and phonetic similarities. Additionally, the initial (A- vs. E-) can both look and sound very similar. However, the endings (-A) vs. (-IN) provide a visual distinction. Additionally, the "U" in Alustra gives the name a longer appearance in the beginning portion of the name (see sample below), providing an added visual distinction. Furthermore, one respondent from the verbal prescription study interpreted the proposed name as "Alastra" and another interpreted the proposed name as "Alestra", which both look and sound like the proprietary name Alustra.

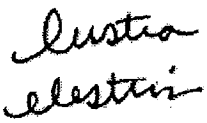


However, per a discussion with Medicis Dermatologics Inc, Alustra was divested to Taro Pharmaceuticals. Via email correspondence with Taro Pharmaceuticals, "Alustra" has been renamed to "Lustra Ultra". Taro also markets "Lustra" and "Lustra AF" (see table 2 below), which lists the differentiating characteristics of the Lustra product line.

Table 2

Ingredient	Lustra	Lustra-AF	Lustra Ultra (previously Alustra)
Hydroquinone 4%	X	X	X
Vitamins / & C	X	X	X
Retinol 0.3%			X
Sunscreen (SPF 20)		X	X
Glycolic Acid	X	X	
Moisturizers	X	X	X

Despite the change in name, the root name Lustra may also look and sound similar to Elestrin. Lustra and Elestrin have the same four overlapping letters in the same position (LUSTRA vs. ELESTRIN). However, the lack of an initial "A" in Lustra gives the name a shorter appearance (see sample below). Additionally, the endings (-A) vs. (-IN) provide a visual distinction. Furthermore, the "U" in Alustra gives the name a longer appearance in the beginning portion of the name, providing an added visual distinction.



Alustra/Lustra and Elestrin have overlapping routes of administration (topical). Additionally they are all available in only one dosage form (topical cream vs. topical gel) and strength (4% vs. 0.06%); and the products can potentially have the directions "Use as directed" or "UD". However, due to the lack of availability of Alustra and the visual and audible differences with Lustra, DMETS believes the risk of confusion between Alustra and Lustrin with Elestrin is minimal.

2. Elimite was found to have look-alike similarities with Elestrin.

   Elimite (permethrin) is topical scabicidal agent indicated for the treatment of *Sarcoptes scabiei* (scabies) infestation. Elimite is available as a 5% cream in 60 gram tubes. It is to be applied thoroughly onto the skin from the head to the soles of the feet (30 grams is usually sufficient for an average adult). The cream should be removed by washing (shower or bath) after 8 to 14 hours. One application is generally curative; however, if living mites are observed after 14 days, retreatment may be necessary.

   Elimite and Elestrin begin with the same two letters (EL-), which contribute to their orthographic similarities. Additionally, the third letters (-I- vs. -E-) can look identical when scripted (see sample below). However, the endings (-MITE vs. -STRIN) provide a distinct visual difference between the two names.

   Elimite #1 UAD

   Elestrin #1 UAD

   elimite
   elestrin

   The two products have an overlapping route of administration (topical). Additionally they are both available in only one dosage form (topical cream vs. topical gel) and strength (5% vs. 0.06%); and both products can potentially have the directions "Use as directed" or "UD". Although there are similar product characteristics and the potential for ambiguously written prescriptions, DMETS believes the visual distinctions in the name will minimize the risk of confusion between Elimite and Elestrin.

3. Elestat was identified as a name that looks and sounds similar to Elestrin.

   Elestat (epinastine) is an ophthalmic antihistamine indicated for the prevention of itching associated with allergic conjunctivitis. Elestat is available as a 0.05% ophthalmic solution and the usual dose is one drop in each eye twice daily. Elestat is supplied in [ ] 10 mL bottles.

   Elestat and Elestrin begin with the same five letters (ELEST-) and have the same number of syllables (three); which contributes to the orthographic (see sample below) and phonetic similarities of this name pair. However, the endings (-AT vs. -RIN) provide visual and audible distinctions between the two names.

   Although Elestat and Elestrin do not have any direct overlapping product characteristics, they are both available in only one dosage form (ophthalmic solution vs. topical gel) and strength (0.05% vs. 0.06%). Thus, allowing for prescriptions to be written without these differentiating characteristics. Additionally both products can potentially have the directions "Use as directed" or "UD".

   elestat
   elestrin

   elestat #1
   UAD

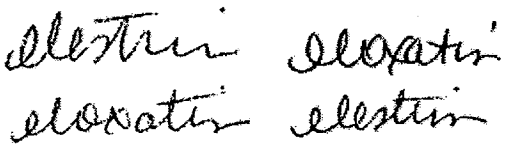
   elestrin #1
   UAD

Although there are similar product characteristics and the potential for overlapping ambiguous prescriptions, due to the orthographically and phonetically distinctive endings, DMETS believes the likelihood for confusion between Elestat and Elestrin is minimal.

4. Eloxatin was identified as a name that looks similar to Elestrin.

   Eloxatin (oxaliplatin) is an antineoplastic agent indicated as adjuvant therapy in the treatment of colorectal cancer. Eloxatin is available in 50 mg and 100 mg single-use vials and the usual dose range is 65 mg/m^2 – 85 mg/m^2 in combination with other antineoplastic agents, given via intravenous infusion over 120 minutes.

   Eloxatin and Elestrin have the same two initial letters (EL-), the same two ending letters (-IN), and the same total number of letters (seven), which contributes to their orthographic similarity (see sample below).

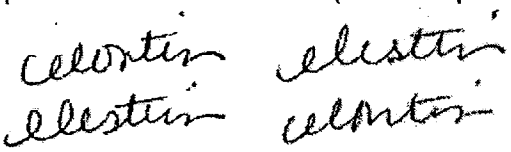
   

   Eloxatin and Elestrin have several differing product characteristics such as dosage form (injection vs. topical gel), route of administration (intravenous vs. topical), available strengths (50 mg, 100 mg vs. 0.06%), frequency of administration (every two weeks vs. once daily), and usual dose (65 – 85 mg/m^2 vs. 1 [ ] actuations [0.87 [ ] grams]). Due to the numerous product differences, DMETS believes the likelihood for confusion between Eloxatin and Elestrin is minimal.

5. Celontin was identified as having look-alike similarities with Elestrin.

   Celontin (methsuximide) is an anticonvulsant agent indicated for the control of absence (petit mal) seizures that are refractory to other drugs. Celontin is available in 150 mg and 300 mg capsules. The usual dose is 300 mg – 1200 mg daily, based on individual patient response.

   The two names have five overlapping letters in similar positions (CELONTIN vs. ELESTRIN). Additionally, the initial portions (CEL- vs. EL-) can look alike when scripted in lower case, when the "C" in Celontin is not written prominently and when the "E" in Elestrin is scripted with a hook in front (see sample below).

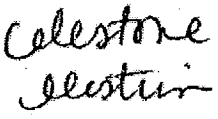
   

   However, Celontin and Elestrin have several differing characteristics such as dosage form (capsule vs. topical gel), route of administration (oral vs. topical), available strength (150 mg, 300 mg vs. 0.06%), and usual dose (300 mg – 1200 mg vs. 1 [ ] actuations [0.87 [ ] grams]). Due to the numerous differing product characteristics, DMETS believes the likelihood for name confusion between Celontin and Elestrin is minimal.

6. Celestone was identified as a name that looks similar to Elestrin.

   Celestone (betamethasone) is a gluocorticoid indicated for use in various endocrine, rheumatic, dermatologic, allergic, ophthalmic, respiratory, hematologic, neoplastic, and gastrointestinal conditions. Celestone is currently available as a 0.6 mg/5 mL oral solution. Celestone was previously available as a 0.2% topical cream, 0.6 mg tablet, and 3 mg base/mL injection; however, these products are no longer marketed and no generic versions of these products are available. The dosage range of Celestone is 0.6 mg – 7.2 mg daily, depending on the specific disease being treated.

   The names Celestone and Elestrin have five overlapping letters in similar positions (CELESTONE vs. ELESTRIN). Additionally the initial portion of the names (CEL- vs. EL-) can look similar when scripted in lower case, when the "C" in Celestone is not written prominently and when the "E" in Elestrin is scripted with a hook in front (see sample below). However, Celestone has a longer appearance, which may help differentiate the two names.

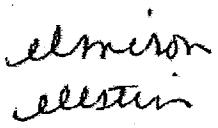
   

   Celestone and Elestrin have an overlapping numeral in their available strengths (0.6 mg/5 mL vs. 0.06%). However, it is unlikely that Celestone will be prescribed using the strength; rather prescribers will write a total volume (e.g. 120 mL or 4 ounces) to be dispensed. Additionally, the two products have differing characteristics such as dosage form (oral solution vs. topical gel), route of administration (oral vs. topical), units of measure for dose (milliliters/teaspoons vs. application/small amount) and usual dose (300 mg – 1200 mg vs. 1[ ] actuations [0.87[ ] grams]). Due to the visual distinction and the differing product characteristics, DMETS believes the likelihood for name confusion between Celestone and Elestrin is minimal.

7. Elmiron was identified as having look-alike similarities with Elestrin.

   Elmiron (pentosan polysulfate sodium) is a low molecular weight heparin-like compound with anticoagulant and fibrinolytic effects. Elmiron is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. The usual dose is 100 mg three times daily and it is available as 100 mg capsules.

   Elmiron and Elestrin begin with the same two letters (EL-), end with the same letter (-N), and have an overlapping letter (-R-) in the third to last position; which contribute to their orthographic similarities (see sample below). However, the letter "T" in Elestrin provides a visual distinction which helps differentiate the two names.

   The products have several differing characteristics such as dosage form (capsule vs. topical gel), route of administration (oral vs. topical), available strength (100 mg vs. 0.06%), usual dose (300 mg vs. 1[ ] actuations [0.87[ ] grams]), and

frequency of administration (three times daily vs. once daily). Due to the product differences, DMETS believes the potential for confusion between Elmiron and Elestrin is minimal.

8. Estring has the potential to sound similar to the proposed name Elestrin.

   Estring (estradiol) is indicated for the treatment of urogenital symptoms associated with postmenopausal atrophy of the vagina and the lower urinary tract and is available as 2 mg vaginal rings which deliver 7.5 mcg of estradiol over 24 hours in a consistent stable manner of 90 days. Estring is to be removed and replaced every 90 days.

   Estring and Elestrin have six overlapping letters (ESTRING vs. ELESTRIN) which gives the names a similar sound when spoken. The sound alike similarities are more apparent when the "G" in Estring and the "EL-" in Elestrin are spoken softly and/or without emphasis. However, Estring and Elestrin do differ with respect to number of syllables (two vs. three), dosage form (vaginal ring vs. topical gel), route of administration (intravaginal vs. topical), available strength (2 mg vs. 0.06%), and frequency of administration (every 90 days vs. once daily). Although the two names can sound similar, DMETS believes the product differences will decrease the chance of confusion and error between the two products.

9. Elaprin*** was identified as a name that sounds similar to Elestrin.

   Elaprin*** is the [ ]
   at the Agency (IND 69,863). Elaprin*** contains Heparin [ ]

   [redacted]

   Elaprin*** and Elestrin begin with the same two letters (EL-) and end with the same three letters (-RIN), which contributes to their phonetic similarities. Additionally, the third letters (-A- vs. -E-) can sound identical when spoken in the middle of a word. However, the middle letters (ela-P-rin vs. ele-ST-rin) give the names an audible distinction from one another.

   The two products differ with respect to dosage form (capsule vs. topical gel), route of administration (oral vs. topical), available strength ([ ] vs. 0.06%), usual dose (/ capsules vs. 1[ ]actuations [0.87[ ] grams]), and frequency of administration ([ ] vs. once daily). Due to the product differences, DMETS believes the potential for confusion and error between Elaprin*** and Elestrin is minimal.

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

Appendix A – DMETS Prescription Study Results for Elestrin

Inpatient	Outpatient	Voice
Elestrin	Rlistrin	Alastra
Elestrin	Electrin	Elistrin
Elestrin	ELECTRIN	Elastrin
Elestrin	Electsin	Elistrin
Elestrin	Elestrin	Ellestran
Elestrim	Electrin	Elestrin
Elestrin	Elestrin	Elistrin
Elestrin	Electrin	Allostrin
Elestrin	Elistrin	Alestra
Elestrim	Elistrin	Alistrin
Elestrin	Elestrin	Alestrin
Elestrin	Elictsin	
	Elestin	
	Elictrin	
	Elestrin	
	Elistrin	
	Elistim	
	Elestrin	
	Elistrin	
	Elistrin	

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/s/

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