

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-738

PROPRIETARY NAME REVIEW(S)

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

DATE RECEIVED: March 13, 2007
DATE OF DOCUMENT:
December 11, 2007

DESIRED COMPLETION DATE:
May 21, 2007
PDUFA DATE: June 12, 2007

OSE REVIEW #:
2007-738

TO: Susan Walker, M.D.
Director, Division of Dermatology and Dental Products
HFD-540

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

FROM: Walter Fava, R.Ph., Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: Extina®
(Ketoconazole) foam 2%

NDA#: 21-738

NDA SPONSOR: Connetics Corporation

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Extina. 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, Extina, 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 correspondence sent to the sponsor concerning the issues outlined in this review. If you have further questions or need clarifications, please contact Angela Robinson, project manager, at 301-796-2284.

**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, LABEL, AND LABELING REVIEW

DATE OF REVIEW: March 22, 2007

NDA#: 21-738

NAME OF DRUG: **Extina**
(Ketoconazole) foam 2%

NDA HOLDER: Connetics Corporation

I. INTRODUCTION:

This consult was written in response to a request from the Division of Dermatology and Dental Products (HFD-540), for a re-assessment of the proprietary name, "Extina", regarding potential name confusion with other proprietary or established drug names. The name Extina was found acceptable by DMETS in OSE consult #'s: 03-0177-1, (dated October 23, 2003), and 03-0177-2 (dated September 13, 2004). DMETS provided label and labeling recommendations in the June 1, 2004 and September 13, 2004 reviews. The revised container label, carton and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Extina (ketoconazole) contains the broad spectrum synthetic antifungal agent ketoconazole. It is indicated for the topical treatment of seborrheic dermatitis. Extina will be supplied as a foam containing 2% ketoconazole supplied in 50 gram and 100 gram aluminum cans. Extina is applied to the affected areas of the skin twice daily for four weeks or until clinical clearing. Patients should dispense a small amount of Extina directly onto the affected area(s), or onto a saucer or other cool surface, taking care to avoid contact with the eyes. The foam will begin to melt upon contact with warm skin. Patients are instructed to rinse their fingers in cold water and dry them thoroughly before handling the foam if their fingers are warm. Extina is for external, topical use only.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of the internet, 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 Extina 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.

¹ MICROMEDEX Integrated Index, 2007, 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 98-07, and the electronic online version of the FDA Orange Book.

⁴ Phonetic and Orthographic Computer Analysis (POCA)

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. 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. 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 (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Extina. 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, Extina, acceptable from a promotional perspective.
2. The Expert Panel identified sixteen additional proprietary names that were thought to have the potential for confusion with Extina. These names are: Exelon, Zetia, Loxitane, Eloxatin, Extingo (foreign), Ex-Lax, Extuss, Exubera, Exotic HC, Exanta***, Ex-Histine, Extraneal, Extin (foreign), Extin N (foreign), Estinyl, and Emtriva.

B. PRESCRIPTION ANALYSIS STUDIES

DMETS conducted prescription analysis studies in consult 03-0177 completed in October, 2003, therefore, prescription analysis studies were not repeated for this re-review.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name, Extina, the primary concern relating to look-alike and sound-alike confusion with Extina are: Exelon, Zetia, Loxitane, Eloxatin, Extingo (foreign), Ex-Lax, Extuss, Exubera, Exotic HC, Exanta***, Ex-Histine, Extraneal, Extin (foreign), Extin N (foreign), Estinyl, and Emtriva.

In the initial analysis of the aforementioned 16 names, it was determined the following 15 names: Exelon, Zetia, Loxitane, Eloxatin, Extingo (foreign), Ex-Lax, Extuss, Exubera, Exotic HC, Exanta***, Ex-Histine, Extraneal, Extin (foreign), Extin N (foreign), and Estinyl not be considered further in this review. for the following reasons. These names were not reviewed further due to lack of convincing look-alike/sound-alike similarities with Extina, in addition to having numerous differentiating product characteristics such as the product strength, indication for use, frequency of administration, route of

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

administration and dosage formulation. The names Extin and Extin N were not reviewed because both of these names are for foreign products.

The remaining name, Emtriva, warranted further evaluation based on look-alike, sound-alike and product characteristics (see Table 1 on page 4).

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

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Extina	Ketoconazole Foam 2%	Apply to affected areas of the skin twice daily for 4 weeks or until clinical clearing. Gently massage into affected areas until foam disappears.	
Emtriva	Emcitabine 200 mg capsule 10 mg/mL oral solution	200 mg orally once a day 240 mg (24 mL) orally once a day	LA

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

Emtriva is discussed in detail below.

The name Emtriva was identified as having look-alike similarities to Extina. Emtriva is a nucleoside reverse transcriptase inhibitor which interferes with the replication of the HIV virus. It is used as part of combination therapy to lower viral load and increase CD₄ cell count.

Emtriva may look similar to Extina because both names have overlapping letters that follow in a similar sequence (**E-M-T-R-I-V-A** vs **E-X-T-I-N-A**). Some of the letters in the names may also look similar when scripted. For example, the letter “x” in Extina, may look similar to the letter “m” in Emtriva, and likewise, the letter “n” in Extina may look like the letter “v” in Emtriva.

However, there are orthographic differences which may help distinguish the name pair. These difference include the difference in the appearance of the letter “m” in Emtriva and the corresponding letter “x” in Extina. Additionally, Emtriva contains the letter “r” which Extina does not have, and the extra letter makes it longer in appearance.

Both products are available in one strength and may therefore be prescribed without specifying the strength. This may add to the potential look-alike confusion between the names. However, since Emtriva is available in two dosage forms (200 mg tablet or 10 mg/mL oral solution), prescribers would need to indicate which dosage form they are ordering, particularly since the usual dosage of the tablet (200 mg) is different from the usual dosage of the oral solution (240 mg or 24 mL). In addition, dosage adjustments based on renal function are needed for Emtriva, so it is likely that prescribers will indicate a dosage for the majority of Emtriva orders. The different dosing and dosage forms of Emtriva may therefore help distinguish it from Extina, which will only be available as a topical 2% foam.

Additionally, the different routes (oral vs topical) and frequency of administration of both products, (once a day vs twice a day), may also help distinguish prescription orders for the two products.

Despite some orthographic similarities between the two names, the potential for confusion between the name pair is minimal because of the different product characteristics.

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III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

Upon review of the revised labels and labeling for Extina, DMETS acknowledges that the sponsor addressed some of the previous recommendations. However, in the interest of minimizing user error and maximizing patient safety, the following comments from DMETS re-iterate previous recommendations as well as include new recommendations.

A. GENERAL COMMENTS

1. Delete the graphic incorporated into the letter "e" of the proprietary "extina". The graphic is distracting and distorts the presentation of the proprietary name.
2. Use the same color font for each letter of the proprietary name, to increase clarity and readability of the proprietary name.

B. CARTON LABEL

1. See General Comments.
2. Differentiate the trade dress proposed for Extina to make it readily distinguishable from other topical foam products marketed by Connetics. It appears the currently proposed colors and graphics used for the label and labeling of Extina, are very similar to another topical foam product, Evoclin (clindamycin phosphate) foam, 1%, as demonstrated in the side by side graphic of the two product carton labels (see below). It is likely that topical products from Connetics such as Extina and Evoclin may be stored in close proximity to each other on the pharmacy shelf, and the look-alike container label/carton labeling may increase the potential for product selection errors to occur. Furthermore, postmarketing surveillance has shown that similar labeling across manufacturers' product lines may increase the potential for product selection errors due to similarity in appearance.

b(4)

Figure 1: Proposed carton labeling for Extina and the approved carton labeling for Evoclin

C. CONTAINER LABEL

1. See General Comments.
2. Relocate the route of administration statement "For Topical Use Only" to the primary display panel.

D. PROFESSIONAL SAMPLE CONTAINER AND CARTON LABEL AND LABELING

1. See General Comments.

E. PACKAGE INSERT LABELING

1. Provide instructions to patients whether or not the product canister should be shaken before use.
2. Incorporate a warning to dispose of unused dose portions in a manner so that the discarded portion is out of the reach of children and pets.

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

/s/

Walter Fava
6/1/2007 04:51:30 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
6/1/2007 04:57:53 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: 4/9/04

DESIRED COMPLETION DATE: 8/04

ODS CONSULT#: 03-0177-1

PDUFA DATE: 11/26/04

TO: Jonathan Wilkin, M.D.
Director, Division of Dermatologic and Dental Drug Products
HFD-540

THROUGH: Lea Carrington
Project Manager
HFD-540

PRODUCT NAME:

Extina™
(Ketoconazole) Foam
2%

NDA: 21-738

NDA SPONSOR:

Connetics Corporation

SAFETY EVALUATOR: Felicia Duffy, RN

DMETS RECOMMENDATIONS:

DMETS recommends implementation of the container label, carton, and insert labeling revisions outlined in the Section II of this review.

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Carol Holquist, RPh
Deputy Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664

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

DATE RECEIVED: May 29, 2003

DESIRED COMPLETION

ODS CONSULT #: 03-0177

DATE OF DOCUMENT: December 17, 2002

DATE: August 22, 2003

TO:

Jonathan Wilkin, MD
Director, Division of Dermatologic and Dental Drug Products
HFD-540

THROUGH:

Frank Cross
Project Manager
HFD-540

PRODUCT NAME:

Extina
(Ketoconazole Foam)
2%

IND SPONSOR: _____

b(4)

IND#: 63,153

SAFETY EVALUATOR: Nora Roselle, PharmD

SUMMARY: In response to a request from the Division of Dermatologic and Dental Drug Products (HFD-540), the Division of Medication Errors and Technical Support (DMETS) conducted a review of the proposed proprietary name, Extina, to determine the potential for confusion with approved proprietary and established names as well as pending names.

DMETS RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Extina. DMETS decision is tentative. This name and its associated labels and labeling must be re-evaluated upon submission of the NDA and 90 days prior to the expected approval of the NDA. A re-review of the name before NDA approval will rule out any objections based upon approvals of other proprietary and established names from this date forward.
2. DMETS recommends implementation of the label and labeling recommendations outlined in section III of this review.
3. DDMAC finds the proprietary name, Extina, acceptable from a promotional perspective.

Carol Holquist, RPh
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Jerry Phillips, RPh
Associate Director
Office of Drug Safety
Center for Drug Evaluation and Research
Food and Drug Administration

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

PROPRIETARY NAME REVIEW

DATE OF REVIEW: October 23, 2003

IND NUMBER: 63,153

NAME OF DRUG: Extina
(Ketoconazole Foam)
2%

IND HOLDER: _____

b(4)

*****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 Dermatologic and Dental Drug Products (HFD-540), to review the proprietary name, Extina, regarding potential name confusion with other proprietary and established names. Container labels, carton and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Extina (Ketoconazole) is indicated for the topical treatment of seborrheic dermatitis. Extina will be supplied as a foam containing 2% ketoconazole supplied in 50 gram aluminum cans. Extina is applied to the affected areas of the skin twice daily for four weeks or until clinical clearing. Patients should dispense a small amount of Extina into the cap of the can, onto a saucer or cool surface or directly onto the lesion(s), taking care to avoid contact with the eyes. The foam will begin to melt upon contact with warm skin. Patients should be instructed to gently massage the foam into the affected areas until the foam disappears. Extina is for external, topical use only.

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 that sound-alike or look-alike to Extina to a degree where potential confusion between drug

¹ MICROMEDEX Integrated Index, 2003, 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, 2003, Facts and Comparisons, St. Louis, MO.

³ The Division of Medication Errors and Technical Support [DMETS] database of proprietary name consultation requests, New Drug Approvals 98-03, and the electronic online version of the FDA Orange Book.

⁴ Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

names could occur under the usual clinical practice settings. The Saegis⁴ 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.

A. EXPERT PANEL DISCUSSION

An Expert Panel Discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Extina. 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. A single product name was identified in the Expert Panel Discussion (EPD) that was thought to have potential for confusion with Extina. This product is listed in Table 1 (see below) along with the dosage forms available and usual FDA-approved dosage. The drug name, Bextra, was identified in the prescription studies conducted by DMETS to have look-alike similarities with the proposed tradename.
2. DDMAC did not have concerns about the name Extina with regard to promotional claims.

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

Product Name	Dosage form(s), Established name	Usual adult dose*	Other
Extina	Ketoconazole Foam, 2%	Apply to affected areas of the skin twice daily for 4 weeks or until clinical clearing. Gently massage into affected areas until foam disappears.	
b(4)	_____	_____	Look-alike
Bextra	Valdecoxib Tablets, 10 mg and 20 mg	<u>Osteoarthritis and Adult Rheumatoid Arthritis:</u> 10 mg once daily <u>Primary dysmenorrhea:</u> 20 mg twice daily, as needed	Look-alike

*Frequently used, not all-inclusive.
 NOTE: This review contains proprietary and confidential information that should not be released to the public.

B. PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

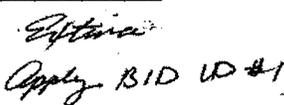
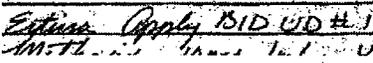
DMETS' Phonetic and Orthographic Analysis (POCA) database was unavailable to search at the time of this review.

C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within FDA for the proposed proprietary names to determine the degree of confusion of Extina 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 127 health care professionals (pharmacists, physicians, and nurses) for each name. These exercises were conducted in an attempt to simulate the prescription

ordering process. Inpatient orders and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Extina (see below). These prescriptions were optically scanned and were 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.

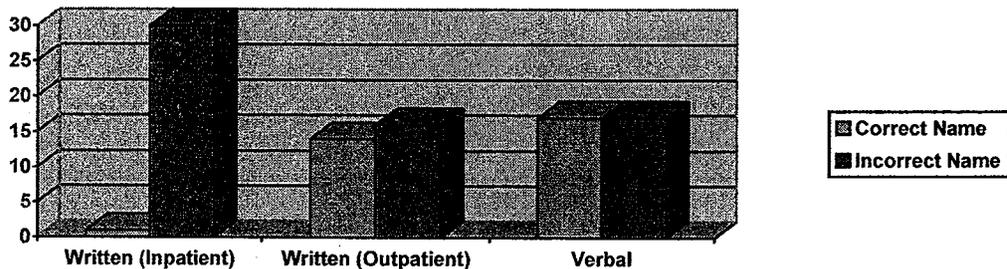
HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: 	Extina Apply twice a day as directed. Dispense one.
Inpatient RX: 	

2. Results:

The results for **Extina** are summarized in Table 2.

Table 2

Study	# of Participants	# of Responses (%)	Correctly Interpreted (%)	Incorrectly Interpreted (%)
Written Inpatient	43	31 (72%)	1 (3%)	30 (97%)
Written Outpatient	41	30 (73%)	14 (47%)	16 (53%)
Verbal	43	34 (79%)	17 (50%)	17 (50%)
Total	127	95 (75%)	32 (34%)	63 (66%)



Among the written inpatient prescription study participants for Extina, 30 of 31 (97%) participants interpreted the name incorrectly. The incorrect responses were *Ertina* (19), *Ertura* (2), *Ertissa* (2), *Eutiva* (1), *Ertiva* (1), *Ertisra* (1), *Etina* (1), *Ertima* (1), *Eytina* (1), and *Ertisa* (1), none of which are names of currently marketed drug products.

Among the written outpatient prescription study participants for Extina, 14 of 30 (47%) participants interpreted the name incorrectly. The incorrect responses were *Extiva* (6), *Extira* (5), *Exteria* (2), *Extirma* (1), *Extevia* (1), and *Extima* (1). None of the incorrect responses are names of currently marketed

drug products. One of the study participants correctly interpreted Extina, but commented that the name "looks a little like Bextra".

Among the verbal prescription study participants for Extina, 17 of 34 (50%) of the participants interpreted the name incorrectly. The incorrect responses were *Extena* (7), *Xtina* (4), *Exteena* (3), *Extinea* (1), *Xteena* (1), and *Xthena* (1), none of which are names of currently marketed drug products.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proposed proprietary name "Extina", the products considered to have potential for name confusion with Extina were _____ and Bextra. b(4)

We conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that Extina could be confused with _____. Bextra. However, negative findings are not always predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to sample size. In addition, one of the written outpatient study participants correctly interpreted Extina, but commented that the name "looks a little like Bextra".

1. _____ has a look-alike similarity to Extina. _____ b(4)

_____ DMETS had no objections to the use of the proprietary name _____, in the original or final reviews in January and June 2001, respectively. _____ is currently under a stay of approval within the Agency. _____

_____ and Extina look similar because they each have the same number and type of letters. Each name contains the letters 'EXT' and differ only in their arrangement at the end of each name _____ b(4)

[] *Extina*

Both drugs may be used twice daily, in some instances be stored in close proximity to one another on some pharmacy shelves, and share an overlapping numerical value in their strengths _____ vs. 2 %). However, _____ is a schedule II controlled substance and will most likely be stored in a locked cabinet. Also, since Extina is only available in a single strength (2%), it is possible that prescribers may not even include it on a script, while prescriptions for _____ will need to include a differentiating strength. In addition _____ and Extina each have a different dosage form _____ vs. foam), route of administration _____ vs. topical), and indication for use _____ vs. seborrheic dermatitis). Even though the two names have similar look and sound alike characteristics, there are numerous product differences which will help diminish the potential for confusion and error. b(4)

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

2. Bextra was identified by one of our study participants to have a look-alike similarity to Extina. Bextra is a COX-2 inhibitor indicated for the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, and for the treatment of primary dysmenorrhea. The recommended dose of Bextra in the treatment of osteoarthritis and rheumatoid arthritis is 10 mg once daily. For the treatment of primary dysmenorrhea, the usual dose is 20 mg twice daily as needed. Bextra is available in 10 mg and 20 mg oral tablets. The handwriting sample used in the outpatient study, that was thought to have look-alike characteristics with Bextra, is shown below. Both names share similar letters including 'EXT' and end in the letter 'A'.

Extina
Apply BID UD #1

Bextra *Extina* *Bextra* *Extina*

Both drugs may be used twice daily and share an overlapping numerical value in their strengths (20 mg vs. 2%). However, there are many differences that help distinguish between the two drugs. Bextra and Extina each have a different dosage form (tablet vs. foam), route of administration (oral vs. topical), and indication for use (arthritis and dysmenorrhea vs. seborrheic dermatitis). In addition, a prescription for Bextra would need to include a distinguishing strength while a prescription for Extina does not require strength since it is only available in a single strength. Based on the above differences, as well as a lack of convincing look-alike similarity, DMETS believes there is a low risk for error between the two drugs.

II. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

DMETS reviewed the container labels, carton, and insert labeling for Extina and has identified the following areas of possible improvement.

A. GENERAL COMMENTS

1. The current draft labels and labeling for Extina have a similar color scheme to the approved 50 g labels and labeling for Olux, and may lead to error and confusion during product stocking and selection. Revise accordingly.
2. The proprietary name, established name, and other text on the labels and labeling are difficult to read. The green background does not provide sufficient contrast to the white colored lettering. The white lettering on the blue background is difficult to read as well. Please revise to increase the readability of all text. We suggest using different contrasting colors or a different color for the lettering.
3. The green colored striped design is distracting and interferes with the readability of the proprietary and established name. Revise accordingly.
4. Decrease the prominence of the term "VersaFoam" and the "V" logo. The phrase and logo appear more prominent than the proprietary name.

5. In addition, DMETS recommends DDDDP consult with the CDER Labeling and Nomenclature Committee (LNC) to determine if the route of administration may be referred to as "_____". The sponsor has used the phrase "_____" on the labels and labeling for this product to indicate the route of administration. However, the term "_____" does not appear in the CDER Data Standards Manual under the listing for Data Element Name: Route of Administration. Other terminology listed in the CDER Data Standards Manual for the Route of Administration that may be appropriate include "Topical" and "Cutaneous". **b(4)**

B. CONTAINER LABELS

1. See comments A1 - A4.
2. We recommend decreasing the prominence of the net quantity so that it has less prominence than the product strength.
3. The "Rx only" statement appears to have more prominence than the proprietary and established names, and the product strength. Revise accordingly.
4. We recommend increasing the prominence of the "Warning" statement by the use of bolding or some other means.

C. CARTON LABELING

1. See comments A1 - A4.
2. See comment B4.

D. INSERT LABELING

No comments at this time.

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IV. RECOMMENDATIONS:

- A. DMETS has no objections to the use of the proprietary name, Extina. DMETS decision is tentative. This name and its associated labels and labeling must be re-evaluated upon submission of the NDA and 90 days prior to the expected approval of the NDA. A re-review of the name before NDA approval will rule out any objections based upon approvals of other proprietary and established names from this date forward.
- B. DMETS recommends implementation of the label and labeling recommendations outlined in section III of this review.
- C. DDMAC finds the proprietary name, _____, acceptable from a promotional perspective. **b(4)**

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 Sammie Beam, Project Manager, at 301-827-3242.

Nora Roselle, PharmD
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

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

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Alina Mahmud
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DRUG SAFETY OFFICE REVIEWER

Carol Holquist
11/12/03 02:22:38 PM
DRUG SAFETY OFFICE REVIEWER

Jerry Phillips
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