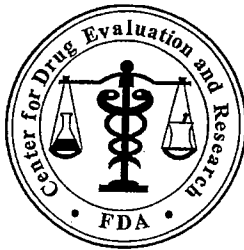


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125338

PROPRIETARY NAME REVIEW(S)



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: February 2, 2010

To: Bob Rappaport, MD, Director
Division of Anesthesia, Analgesia, and Rheumatology Products

Through: Carlos Mena-Grillasca, RPh, Team Leader *CMena 2/2/2010*
Denise P. Toyer, PharmD, Deputy Director *Denise P. Toyer 2/2/10*
Division of Medication Error Prevention and Analysis (DMEPA)

From: Walter Fava, R.Ph., MSED., Safety Evaluator *Walter Fava 2-2-10*
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Xiaflex (Collagenase Clostridium Histolyticum) for Injection
0.9 mg per vial

Application Type/Number: BLA 125338

Applicant: Auxilium Pharmaceuticals, Inc.

OSE RCM #: 2010-221

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1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of this BLA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Xiaflex, acceptable in OSE Reviews #2009-1306, dated September 9, 2009. The Division of Anesthesia, Analgesia, and Rheumatology Products did not have any concerns with the proposed name, Xiaflex, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on July 7, 2009.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review #2009-1306. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases referenced in Section 4 did not yield any new names thought to look or sound similar to Xiaflex and represent a potential source of drug name confusion.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Xiaflex, as of January 28, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The proprietary name risk assessment findings indicate that the proposed name, Xiaflex, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Xiaflex, for this product at this time.

DMEPA considers this a final review; however, if approval of the BLA is delayed beyond 90 days from the date of this review, the Division of Anesthesia, Analgesia, and Rheumatology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE review # 2009-1306 dated September 9, 2009; Proprietary Name Review of Xiaflex; Walter Fava, Safety Evaluator.

2. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

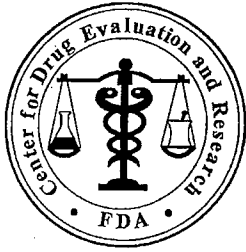
Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

3. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

4. ***CDER Proposed Names List***

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: March 5, 2008

To: Bob A. Rappaport, MD, Director
Division of Anesthesia, Analgesia and Rheumatology Products

Thru: Linda Y. Kim-Jung, PharmD., Team Leader
Division of Medication Errors and Prevention

From: Denise V. Baugh, PharmD, BCPS, Safety Evaluator

Subject: Proprietary Name Review

Drug Name(s): Xiaflex (primary)
(b) (4)
(Clostridial Collagenase) 0.58 mg for Injection

Application Type/Number: IND# 5780

OSE RCM #: 2007-1706 and 2007-1707

1 INTRODUCTION

This memorandum is in response to an August 2, 2007 request from your Division for a review of the proposed proprietary names, Xiaflex (primary) and (b) (4) (secondary).

2 DISCUSSION

During the initial steps of the proprietary name review process (EPD), the Division of Drug Marketing, Advertising and Communications (DDMAC) did not recommend the use of the proposed proprietary names, (b) (4) (primary) and (b) (4) (secondary) because they overstate the efficacy of the drug product by misleadingly implying it is superior to other treatment.

DDMAC provided the following comments:

Xiaflex

DDMAC objects to the proposed trade name "Xiaflex" because it overstates the efficacy of the drug product. "Xiaflex" contains "flex" which evokes the word "flexible," which is defined as "able to bend or to be bent easily without breaking"

(<http://dictionary.cambridge.org/define.asp?key=29618&dict=CALD>; accessed 8/15/07).

The proposed indication for this drug product is for the treatment of Dupuytren's contracture: Dupuytren's contracture is a rare hand deformity in which the connective tissue (fascia) under the skin of the palm thickens and scars. Knots (nodes) and cords of tissue form under the skin, often pulling one or more of the fingers into a bent (contracted) position. Though the fingers affected by Dupuytren's contracture bend normally, they can't be straightened, making it difficult to use your hand (MayoClinic.com; <http://www.mayoclinic.com/health/dupuytren-s-contracture/DS00732>; accessed 8/15/07). The proposed trade name implies that treatment with AA4500 will allow patients to bend their fingers or bend their fingers easily. In the absence of substantial evidence to support such a treatment response, the proposed trade name is misleading.

(b) (4)

(b) (4)

Please note that the Federal Food Drug and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a trade name or otherwise; this includes suggestions that a drug is better, more

effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)].

3 CONCLUSIONS AND RECOMMENDATIONS

As per email correspondence with the Division of Anesthesia, Analgesia and Rheumatology Products on March 4, 2008, the Division concurs with DDMAC's comments. Therefore, DMETS will not proceed with the safety review of the proposed proprietary names, Xiaflex (primary) and (b) (4) (secondary), since the Division supports DDMAC's objection of the name based on promotional concerns.

If you have any questions for DDMAC, please contact Carrie Newcomer and Michelle Safarik 301-796-1200. If you have any other questions or need clarification, please contact the Division of Anesthesia, Analgesia and Rheumatology Products' OSE project manager, Darrell Jenkins, at 301-796-0558.

Linked Applications

Sponsor Name

Drug Name

IND 5780

AUXILIUM
PHARMACEUTICALS

Collagenase (C. histolyticum, Advance
Biofactures)

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

/s/

DENISE V BAUGH

03/06/2008

Administrative

LINDA Y KIM JUNG

03/06/2008

Epidemiology and Post Marketing Reviewer