

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202570Orig1s000

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
Office of Medication Error Prevention and Risk Management**

Date: August 3, 2011

Application Type/Number: NDA 202570

Through: Todd Bridges R.Ph., Team Leader
Carol Holquist, R.Ph., Director
Division of Medication Error Prevention and Analysis

From: Kevin Wright, Pharm.D., Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name(s): Xalkori (crizotinib) capsules
200 mg and 250 mg

Applicant: Pfizer Pharmaceuticals, Inc.

OSE RCM #: 2011-2590

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Xalkori, responds to the anticipated approval of NDA 202570 within 90 days from the date of this review. In OSE Review #2011-1168 dated June 2011, the proprietary name, Xalkori, was found acceptable.

2 METHODS

For the proposed proprietary name, Xalkori, DMEPA safety evaluators search a standard set of databases and information sources (see section 5) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. The safety evaluator did not evaluate the names identified in the previous reviews because none of the product characteristics have been altered since the time of the last review. For this re-assessment, we used the same search criteria outlined in our previous OSE reviews.

Additionally, DMEPA searched the 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. DDMAC re-assessed the proposed name on April 14, 2011.

3 RESULTS

The safety evaluator's search of the databases listed in Section 5 did not identify any additional names orthographically, phonetically, or having shared characteristics to Xalkori. Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 1, 2011.

Additionally, DDMAC had no concerns regarding the proposed name from a promotional perspective.

4 CONCLUSIONS

The Proprietary Name Risk Assessment identified that the proposed name, Xalkori, is not vulnerable to name confusion that could lead to medication errors nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Xalkori, for this product.

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

This document contains proprietary and confidential information that should not be released to the public.

5 REFERENCES

1. Baugh, D; OSE review #2010-1790, Proprietary Name Review of Xalkori (Crizotinib), February 8, 2011.
2. Baught, D; OSE review #2011-1168 Proprietary Name Review of Xalkori (Crizotinib), June 27, 2011.
3. **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.
4. **USAN Stems** (<http://www.ama-assn.org/ama/pub/category/4782.html>)
USAN Stems List contains all the recognized USAN stems.
5. **Division of Medication Error Prevention and Analysis proprietary name requests**
This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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/s/

KEVIN S WRIGHT
08/03/2011

TODD D BRIDGES
08/03/2011

CAROL A HOLQUIST
08/03/2011

**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: June 27, 2011
Application Type/Number: NDA 202570
To: Robert Justice, MD, Director
Division of Drug Oncology Products
Through: Todd Bridges, RPh, Team Leader
Kellie Taylor, PharmD, Associate Director
Division of Medication Error Prevention and Analysis (DMEPA)
From: Denise V. Baugh, PharmD, BCPS, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)
Subject: Proprietary Name Reconsideration Request Review
Drug Name and Strengths: Xalkori (Crizotinib) Capsules
200 mg and 250 mg
Applicant: Pfizer Pharmaceuticals, Inc.
OSE RCM #: 2011-1168

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EXECUTIVE SUMMARY

This review summarizes the Division of Medication Error Prevention and Analysis' (DMEPA) evaluation of the request for reconsideration of the proposed proprietary name, Xalkori. DMEPA concluded in OSE Review 2010-1790, dated February 8, 2011, that the name is unacceptable due to orthographic and/or phonetic similarity and shared product characteristics to the marketed names, Voltaren and Valturna, as well as with (b) (4) a proposed proprietary name for a pending application. The original submission provided for a (b) (4) product strength for Xalkori. In their request for reconsideration of the name, the Applicant states that they will no longer pursue this strength and therefore, there is less potential for confusion between Xalkori and these names.

In their response, the Applicant submitted an independent safety analysis conducted by (b) (4) in support of the proposed proprietary name, Xalkori. Upon analysis of the information provided by the Applicant, we believe elimination of the (b) (4) strength helps to minimize the possibility of confusion between Xalkori vs. Voltaren and Xalkori vs. Valturna. We also determined that the proposed proprietary name for a pending application, (b) (4) is no longer a potential source of confusion with the name, Xalkori.

Therefore, we have reconsidered our original decision and now have no objections to the use of the proprietary name, Xalkori, for this product at this time.

1.1 INTRODUCTION

This review responds to a March 31, 2011, request from Pfizer Pharmaceuticals, Inc. to reconsider the proposed proprietary name, Xalkori, for NDA 202570.

1.2 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed name, Xalkori, unacceptable in OSE Review 2010-1790 based on orthographic and/or phonetic similarity and shared product characteristics to the marketed names, Voltaren and Valturna, as well as well as with (b) (4) a proposed proprietary name for a pending application. The Applicant was notified of our decision in writing via letter dated February 8, 2011. The Applicant submitted a request for reconsideration of the proposed proprietary name, Xalkori, on March 31, 2011.

2 METHODS AND MATERIALS

DMEPA reviewed Pfizer Pharmaceutical, Inc's request for reconsideration, which includes an external study completed by (b) (4) in support of the use of the proprietary name, Xalkori (b) (4) as well as our initial review of the proposed proprietary name, Xalkori (OSE Review 2010-1790). We also evaluated the status of the proposed proprietary name for a pending application, (b) (4) to determine if the name is still a potential source of confusion with the name, Xalkori.

3 RESULTS AND DISCUSSION

The external study provides information in support of the use of Xalkori as a safe and acceptable proprietary name candidate for crizotinib.

In their request to re-evaluate this name, the Applicant proposes that the decision to withdraw the (b)(4) strength for Xalkori from the application changes the vulnerability of Xalkori to confusion with the marketed names, Voltaren and Valturna by reducing the dosing strength similarity.

3.1 LOOK-ALIKE SIMILARITY OF XALKORI AND VOLTAREN

In our initial review of the proposed name, we determined that the (b)(4) dose of Xalkori could be achieved with the available product strengths of Voltaren (or generic equivalent). Considering the Applicant's commitment not to pursue the (b)(4) product strength for Xalkori, we completed a preliminary drug usage data profile to determine if the remaining 200 mg and 250 mg doses of Xalkori (which are achievable with the available product strengths of generic Voltaren) may contribute to confusion between the names Xalkori and Voltaren. The drug usage information retrieved indicates that prescribers are not ordering daily doses of Voltaren above 200 mg (SDI's Vector Alpha database). Therefore, we are in agreement with the Applicant that a prescription for Xalkori 200 mg or 250 mg twice daily is unlikely to be misinterpreted as Voltaren 200 mg or 250 mg twice daily since this exceeds the 200 mg maximum recommended daily dose for Voltaren by 200 mg or more.

3.2 LOOK-ALIKE SIMILARITY OF XALKORI AND VALTURNA

In our previous analysis of the name Xalkori, (b)(4) Valturna (150 mg/160 mg) and (b)(4) Xalkori (b)(4) risk of proprietary name confusion between Xalkori and Valturna. Since the (b)(4) product strength will no longer be pursued by the Applicant, our concern regarding confusion between this name pair is minimized.

3.3 LOOK-ALIKE SIMILARITY OF XALKORI AND PROPOSED PROPRIETARY NAME PENDING IN THE AGENCY

(b)(4) the proposed proprietary name for a pending application (NDA (b)(4)), was found to be orthographically and phonetically similar to the proposed name, Xalkori. Subsequently, the proposed name, (b)(4) was found to be unacceptable by DMEPA because of orthographic similarity and shared product characteristics with the marketed product, Zolinza. Additionally, the current application status for the (b)(4) product is "refuse to file". The Applicant has expressed their intentions to resubmit the application in the fall of 2011, whereas the action date for the Xalkori application is August 29, 2011.

Therefore, this name is no longer considered to be a name with potential for confusion with Xalkori.

4 CONCLUSIONS AND RECOMMENDATIONS

Our analysis of the information provided by the Applicant in support of reconsideration of the proposed proprietary name, Xalkori, determined the elimination of the (b)(4) strength from the application decreases the likelihood of confusion between Xalkori and the marketed names Voltaren and Valturna. Additionally, the proposed proprietary name for a pending application, (b)(4) is no longer considered to be a name with potential for confusion with Xalkori.

Therefore, we have reconsidered our original decision and now have no objections to the use of the proprietary name, Xalkori, for this product.

If you have any questions or need further clarification, contact Sarah Simon, OSE Project Manager, at 301-796-5205.

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Xalkori, and have concluded that it is acceptable.

The proposed proprietary name, Xalkori, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Sarah Simon, Regulatory Project Manager in the Office of Surveillance and Epidemiology, at 301-796-5205. For other information regarding this application contact Diane Hanner, OND Regulatory Project Manager at 301-796-4058.

REFERENCES

1. Baugh, Denise. Proprietary Name Review, Xalkori (Crizotinib) Capsule, (b) (4) 200 mg, and 250 mg, OSE Review 2010-1790, dated February 8, 2011.
2. Preliminary drug usage data retrieved by Lubna Merchant on June 22, 2011, from SDI's Vector Alpha database.

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/s/

TODD D BRIDGES on behalf of DENISE V BAUGH
06/24/2011

KELLIE A TAYLOR
06/27/2011