

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207768Orig1s000

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**

Proprietary Name Memorandum

Date: September 14, 2014

Reviewer: Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Associate Director: Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Tuzistra XR (Codeine Polistirex and Chlorpheniramine
Polistirex) Extended-release Suspension
20 mg/4 mg per 5 mL

Application Type/Number: NDA 207768

Applicant: Tris Pharma Inc.

OSE RCM #: 2014-25824

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

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1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Tuzistra XR, under NDA 207768. DMEPA previously found the name acceptable in OSE Review # 2014-16675 dated May 27, 2014 for IND (b) (4). (b) (4) 10 mL every 12 hours) for NDA 207768. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessments of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review # 2014-16675. Additionally, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in dosage. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 11, 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

We have completed our review of the proposed proprietary name, Tuzistra XR, and have concluded that this name is acceptable.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE Project Manager, at 301-796-3904.

3.1 Comments to the Applicant

We have completed our review of the proposed proprietary name, Tuzistra XR, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your July 9, 2014 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. Owens, L, Proprietary name review for Tuzistra XR (IND (b) (4)). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014-05-27. OSE RCM No.: 2014-16675.
2. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
3. **Phonetic and Orthographic Computer Analysis (POCA)**
POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

LISSA C OWENS
09/14/2014

LUBNA A MERCHANT
09/15/2014