

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

NDA 22-249

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: March 18, 2008

To: Robert Justice, MD
Director, Division of Drug Oncology Products,
HFD-150

Thru: Denise Toyer, PharmD, Deputy Director
Division of Medication Error Prevention

From: Kristina C. Arnwine, PharmD, Acting Team Leader
Division of Medication Error Prevention

Subject: Proprietary Name, Label, and Labeling Review

Drug Name: Treanda (Bendamustine Hydrochloride) for Injection, 100 mg

Application Type/Number: NDA # 22-249

Applicant/sponsor: Cephalon, Inc

OSE RCM #: 2007-2064

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1 INTRODUCTION

This memo is written in response to a request from the Division of Drug Oncology Products (HFD-150), for clarification with regard to a typographical error in OSE 2007-2064.

2 MATERIAL REVIEWED

OSE review 2007-2064, dated March 10, 2008.

3 DISCUSSION

We note that Appendix D entitled "Products with no numerical overlap in strength and dose" contains the incorrect established name for the proposed product, Treanda. Appendix D lists the established name as "(choline fenofibrate)", rather than the correct established name "(bendamustine hydrochloride)". However, all of the information in Appendix D pertaining to Treanda is based on the established name bendamustine hydrochloride. Please see the revised appendix below.

4 CONCLUSIONS

In Appendix D, the correct established name for the proposed product, Treanda, should read "(bendamustine hydrochloride)".

If you have any questions or need clarifications, please contact Janet Anderson, OSE Project Manager, at (301) 796-0675.

Appendix D: Products with no numerical overlap in strength and dose.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Treanda (Bendamustine Hydrochloride)		100 mg	Usual dose: 100 mg/m ² given on days 1 and 2 of a 28-day cycle
Trental	Look and Sound	400 mg	One tablet by mouth three times daily with meals
Trionate	Look	60 mg/5 mg	One tablet by mouth twice daily
Trinate	Look	Prenatal Multi-vitamin	One tablet by mouth once daily
Tripedia	Look	6.7 Lf/ 46.8 mcg/ 5 Lf/ 0.5 mL	0.5 ml as a 5-dose series in infants and children 6 weeks to 7 years of age.
Triant HC	Look	2 mg/1.67 mg/5 mg	1 teaspoonful to 2 teaspoonsful by mouth every 4 to 6 to 8 hours as needed
Ziana	Sound	1.2/0.025% gel	Apply topically to affected area at bedtime
Trientine	Sound	250 mg	750 mg to 1250 mg by mouth per day in 2 to 4 divided doses

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/s/

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3/18/2008 04:52:01 PM
DRUG SAFETY OFFICE REVIEWER

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3/18/2008 04:54:24 PM
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