

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209570Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review: August 10, 2017
Application Type and Number: NDA 209570
Product Name and Strength: (b) (4) (benznidazole) tablet
12.5 mg tablet and 100 mg tablet
Product Type: Single
Rx or OTC: Rx
Applicant/Sponsor Name: Chemo Research, S. L.
Panorama #: 2017- 16447196
DMEPA Primary Reviewer: Sevan Kolejian, Pharm D
Acting DMEPA Team Leader: Otto L. Townsend, Pharm D
Deputy Director: Irene Z. Chan, PharmD, BCPS
DMEPA Director: Todd Bridges, RPh

1 INTRODUCTION

This review evaluates the proposed proprietary name, (b) (4), for NDA 209570. The proposed proprietary name was submitted by Chemo Research, S. L. for evaluation on July 19, 2017. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) on January 5, 2017. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) unacceptable due to orthographic and overlapping product characteristics with the proprietary name, (b) (4) in OSE Review # (b) (4), dated March 15, 2017. Subsequently, the Applicant submitted the name, (b) (4), for review on April 7, 2017. DMEPA notified the Applicant of our preliminary finding that the proposed proprietary name, (b) (4), was unacceptable during a teleconference meeting dated June 16, 2017. The Applicant withdrew the request for review of proprietary name, (b) (4) on June 29, 2017 and submitted the request for the proposed proprietary name, (b) (4) on July 19, 2017.

2 PRODUCT INFORMATION

The following product information is provided in the July 19, 2017 proprietary name submission.

- Intended Pronunciation: (b) (4)
- Active Ingredient: benznidazole
- Indication of Use: an antiprotozoal indicated for the treatment of Chagas disease
- Route of Administration: oral
- Dosage Form: The product will be available as 12.5 mg oral tablets and 100 mg functionally scored oral tablets.
- Strength: 100 mg tablet and 12.5 mg tablet.
- Dose and Frequency: The dose is based on the patient's body weight (b) (4) (b) (4). (u) (4) The dosing recommendation is under review and the dose for patients between 2-12 years of age is (b) (4) 5-8 mg/kg/day. The daily dose should be divided (b) (4) and administered (u) (4) 12 hours.
- How Supplied:
 - 100 mg tablets -- available in packages of 100 tablets.
 - 12.5 mg tablets -- available in packages of 100 tablets.
- Storage: Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep bottle tightly closed and protect from moisture. (b) (4)
- Container and Closure Systems: The product (tablets) will be distributed by the manufacturer in high density polyethylene (HDPE), white, (b) (4) bottles of either 75 cc or 30 cc, for the 100 mg or 12.5 mg tablets, respectively. The bottles use a (b) (4) cap and contain 100 tablets per bottle.

3 DISCUSSION

During the initial steps of the proprietary name review process, the Office of Prescription Drug Promotion (OPDP) did not recommend the use of the proposed proprietary name (b) (4) because it would misbrand the proposed product. OPDP provided the following statement:

OPDP objects to the proposed proprietary name (b) (4) because, as proposed, it would overstate the efficacy of the drug and minimize the risks associated with the drug. The proposed proprietary name contains the word (b) (4) which is defined as (b) (4)

*(<http://unabridged.merriam-webster.com/unabridged>, (b) (4), accessed 7/25/17). According to the current version of the draft product labeling this drug is indicated, “in pediatric patients (2 to 12 years of age) for the treatment of American Trypanosomiasis (Chagas disease) caused by *Trypanosoma cruzi*. This indication is approved under accelerated approval based on (b) (4) (b) (4) the number of treated patients who became IgG antibody negative against the recombinant antigens of *T. cruzi*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. . . .” The proposed proprietary name may misleadingly suggest (b) (4)*

(b) (4) Therefore, the proposed proprietary name (b) (4) would be misleading.

This concern was shared with the Division of Anti-Infective Products (DAIP). In email correspondence dated August 3, 2017, DAIP concurred with OPDP’s assessment. DMEPA also concurs with this finding and will not perform a safety assessment of the proposed proprietary name.

4 CONCLUSIONS AND RECOMMENDATIONS

The proposed proprietary name, (b) (4), is unacceptable as it would misbrand the proposed product. The Applicant will be notified of FDA’s decision to object to the name via letter.

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, (b) (4) and have concluded that this name is unacceptable for the following reason:

We object to the proposed proprietary name (b) (4) because, as proposed, it would overstate the efficacy of the drug and minimize the risks associated with the drug. The proposed proprietary name contains the word (b) (4) which is defined as (b) (4)

*(<http://unabridged.merriam-webster.com/unabridged>, (b) (4) accessed 7/25/17). According to your draft product labeling this drug is indicated, “in pediatric patients (2 to 12 years of age) for the treatment of American Trypanosomiasis (Chagas disease) caused by *Trypanosoma cruzi*. This*

indication is approved under accelerated approval based on (b) (4) the number of treated patients who became IgG antibody negative against the recombinant antigens of T. cruzi. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. . . .” The proposed proprietary name may misleadingly suggest (b) (4)

(b) (4) However, the draft product labeling does not include any information to support this benefit or conclusion. We are not aware of clinical trials being designed and conducted to support such a conclusion. Furthermore, (b) (4)

(b) (4)

(b) (4) Therefore, the proposed proprietary name (b) (4) would be misleading.

Please note that the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). The FD&C Act also provides that a drug is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading, such as by making misrepresentations with respect to safety or efficacy.

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/s/

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08/10/2017

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Date of This Review: March 15, 2017
Application Type and Number: NDA 209570
Product Name and Strength: (b) (4) (benznidazole) tablet
12.5 mg tablet and 100 mg tablet
Product Type: Single
Rx or OTC: Rx
Applicant/Sponsor Name: Chemo Research, S. L.
Panorama #: 2017-12352649
DMEPA Primary Reviewer: Sevan Kolejian, PharmD
DMEPA Team Leader: Vicky Borders-Hemphill, PharmD
Acting DMEPA Deputy Director: Danielle Harris, PharmD, BCPS
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