CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208143Orig1s000

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:	March 19, 2015
Application Type and Number:	NDA #208143
Product Name and Strength:	Readi-Cat 2 [(Barium Sulfate) Oral Suspension 2% w/v] Readi-Cat 2 Smoothie [(Barium Sulfate) Oral Suspension 2% w/v]
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Bracco Diagnostics Inc.
Panorama #:	2015-46935 and 2015-46936
DMEPA Primary Reviewer:	Leeza Rahimi, Pharm.D.
DMEPA Team Leader:	Yelena Maslov, Pharm.D.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Readi-Cat 2 and Readi-Cat 2 Smoothie, from a safety and misbranding perspective. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Readi-Cat 2 and Readi-Cat 2 Smoothie have been in the US Market since 1985. However, these products have never been approved by the FDA. As a result, on January 8th, 2015 Bracco submitted an NDA for Readi-Cat 2 (barium sulfate) oral suspension, 2% w/v and Readi-Cat 2 Smoothie (barium sulfate) oral suspension, 2% w/v and proposed proprietary name review for the products.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 8th, 2015 proprietary name submission.

- Intended Pronunciation: Ready-Cat-2, Ready-Cat 2 Smoothie
- Active Ingredient: Barium Sulfate
- Indication of Use: Indicated for use in Computed Tomography of the abdomen (b) (4)
- Route of Administration: Oral
- Dosage Form: Oral Suspension
- Strength: 2% (w/v)
- Dose and Frequency: Typical adult dose can range from 450-900 mL of product
- How Supplied: Readi-Cat-2 products are supplied as a unit dose in single use HDPE plastic bottle containing 450 mL of 2% (w/v) barium sulfate suspension for oral administration. Readi-Cat 2 Smoothies are provided in four (4) flavors, Banana, Berry, Creamy Vanilla, and Mochaccino. Readi-Cat 2 is provided as an Orange flavor.
- Storage: Room temperature 20 to 25 degrees Celcius (68 to 77 degrees Fahrenheit)
- Container and Closure Systems: Single use HDPE plastic bottle of 24 x 450 mL

Reference ID: 3721385

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Medical Imaging Products (DMIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The proprietary names are comprised of the root name Readi-cat and the modifier 2 and 2 Smoothie. The Applicant provided an intended meaning of the proprietary names as follows: The number 2 in the name refers to the 2% barium sulfate contained in the product. The original Readi-Cat 2 formula was improved upon with the Smoothie formula by adding a (b) (4) which gave the product a smoother sensation when swallowed; the product also has an appearance alike to smoothie beverage; hence the addition of Smoothie to the product name.

Typically, FDA discourages the use of numerals within a proprietary name, as misinterpretations of numerals as strength and/or dose may lead to medication errors.

We note that this product has been on the market for over 30 years. As noted in section 2.2.3, we have not identified any post-marketing cases or signals related to name confusion with this. Furthermore, this product is used by a specific healthcare practitioner specialty who are already familiar with the product's names. Changing the proprietary name of the product at this point may introduce confusion among the medical community given the familiarity of this community with the barium products. Moreover, in the meeting that occurred between DMEPA and DMIP in early 2014, DMIP also noted that they prefer to keep the current names for all the barium products.

2.2.3 Medication Error Data Selection of Cases

Even though this product is an unapproved product, but has been in the market since 1985. As a result, we searched the FDA Adverse Event Reporting System (FAERS)

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[1]USAN stem search conducted on January 9th, 2015.

Reference ID: 3721385

database using the strategy listed in Table 2 (see Appendix A for a description of FAERS database) for name confusion errors involving Readi-Cat 2 which would be relevant for this review.

Table 2. FAERS Search Strategy	
Date	March 18, 2015
Drug Name(Product Name)	Readi-Cat-2
MedDRA Event Search	Medication Errors-HLGT
Time/Date Limits	January 01, 1985 through March 18, 2015

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, none of the reports identified noted any cases of name confusion with the proprietary names and thus were not relevant to this review.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, on January 21st, 2015 e-mail, the Division of Medical Imaging Products (DMIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Medical Imaging Products (DMIP) via e-mail on March 23rd, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMIP on February , they stated no additional concerns with the proposed proprietary name, Readi-Cat 2 and Readi-Cat 2 Smoothie.

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3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Vasantha, Ayala, OSE project manager, at **240-402-5035**.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Readi-Cat-2, and Readi-Cat-2 Smoothie, and have concluded that this name is acceptable.

REFERENCES

1. ***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.

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/s/

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03/25/2015

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03/25/2015