CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202153Orig1s000

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:	March 8, 2016
Reviewer:	Michelle Rutledge, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Yelena Maslov, PharmD Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Ruby-Fill (Rubidium Rb-82 Generator) Injection
Application Type/Number:	NDA 202153
Applicant/sponsor:	Jubilant Draximage, Inc
OSE RCM #:	2015-2442718

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CONTENTS

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Ruby-Fill, under NDA 202153, which was found acceptable in previous OSE Reviews# 2014-17160[1] and 2010-1489 and 2010-1495[2]. The Applicant did not submit an external name study for this proposed proprietary name, however the applicant did submit a list of drugs reviewed containing the term 'rubi' in their tradename (See Appendix A).

2 METHODS AND DISCUSSION

To re-assess the proposed proprietary name, the Division of Medication Error Prevention and Analysis (DMEPA), conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name reviews #2014-17160 and #2010-1489 and 2010-1495. 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. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, the Applicant submitted seven names that contained the letter string 'rubi' in the names. None of those names represent a potential source of confusion (See Appendix A). Furthermore, our POCA search identified a new proposed proprietary name (b) (4) *** that does not represent a potential source of drug name confusion (see Appendix B). 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 March 7, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

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

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Ruby-Fill, and have concluded that this name is acceptable.

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[1] Rutledge M. Proprietary Name Review Memorandum for Ruby-Fill (NDA 202153). 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 Apr 1. 4 p. OSE RCM 2014-17160

[2] Merchant L. Proprietary Name, Label and Labeling Review for Ruby-Fill (ANDA 202153). 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); 2010 Dec 16. 25 p. OSE RCM 2010-1489 and 2010-1495.

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

4 REFERENCES

1. Rutledge M. Proprietary Name Review Memorandum for Ruby-Fill (NDA 202153). 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 Apr 1. 4 p. OSE RCM 2014-17160
2. Merchant L. Proprietary Name, Label and Labeling Review for Ruby-Fill (ANDA 202153). 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); 2010 Dec 16. 25 p. OSE RCM 2010-1489 and 2010-1495.
3. 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.

APPENDICES

Appendix A: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Berubigen	36
2.	Cerubidine	34
3.	Daunorubicin hydrochloride	15
4.	Doxorubicin	32
5.	Epirubicin hydrochloride	17
6.	Idarubicin hydrochloride	17
7.	Varubi	37

Appendix B: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) *** (Phonetic Score: 83)	68	This name was identified in the Name Entered by Safety Evaluator database. However, the proposed proprietary name was withdrawn by the Applicant after being found acceptable in OSE Review#2011-4562. IND 079726 is pending.

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/s/

MICHELLE K RUTLEDGE
03/08/2016

YELENA L MASLOV
03/09/2016

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:	April 1, 2014
Reviewer:	Michelle Rutledge, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Yelena Maslov, PharmD Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Ruby-Fill (Rubidium Rb-82 Generator) Injection
Application Type/Number:	NDA 202153
Applicant/sponsor:	Jubilant Draximage, Inc
OSE RCM #:	2014-17160

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CONTENTS

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Ruby-Fill, under NDA 202153, in response to a request from the Division of Medical Imaging Products (DMIP). DMEPA previously found the name acceptable in OSE Review# 2010-1489 and 2010-1495 dated December 16, 2010.

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 #2010-1489 and 2010-1495. 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. 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 April 1, 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, Ruby Fill, and have concluded that this name is acceptable.

If you have further questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE Project Manager, at 240-402-5035.

4 REFERENCES

1. ANDA 202153 Propriety name, label and labeling review dated December 17, 2010 (*OSE Review 2010-1489* & OSE Review 2010-1495)

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/

MICHELLE K RUTLEDGE
04/02/2014

YELENA L MASLOV
04/02/2014

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:	December 16, 2010
Application Type/Number:	ANDA 202153
To:	Peter Rickman, Director Division of Labeling Review Branch Office of Generic Drugs
Through:	Melina Griffis RPh, Team Leader Denise Toyer, Pharm.D., Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Lubna Merchant MS, Pharm.D, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name, Label and Labeling Review
Drug Name(s):	Ruby-Fill (Rubidium Rb-82 Generator) Injection
Applicant:	Draximage
OSE RCM #:	2010-1489 and 2010-1495

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CONTENTS

EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, labels, and labeling for Ruby-Fill (Rubidium Rb-82 Generator) Injection. Our evaluation of the proposed proprietary name Ruby-Fill did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Ruby-Fill conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the ANDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

Our label and labeling risk assessment indicates the presentation of information on the proposed labels and labeling introduces vulnerability to confusion that can lead to medication errors. We provide label and labeling recommendations in section 5 of this review.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Draximage. dated June 21, 2010, for an assessment of the proposed proprietary name, Ruby-Fill, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. Additionally, the Applicant submitted container label for review as part of the ANDA submission, which we evaluated to identify vulnerabilities that may cause confusion leading to medication error.

1.2 PRODUCT INFORMATION

Ruby-Fill (Rubidium Rb-82 Generator Injection) is a PET radiopharmaceutical for cardiac perfusion imaging. It will be prescribed by a cardiologist to outpatient, or in a hospital setting for cardiac perfusion tests. Ruby-Fill is administered by injection using a product specific (b) (4) system, capable of accurately measuring and delivering the desired activity of Rubidium Rb-82 Chloride Injection. (b) (4) Ruby-Fill is supplied in the form of strontium Sr 82 adsorbed on a hydrous stannic oxide column with an activity of (b) (4) mCi and is enclosed in a lead shield. Cardiogen-82 is the reference-listed drug for Ruby-Fill.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Ruby-Fill. Section 2.3 identifies specific information associated with the methodology for assessment of the proposed labels and labeling.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'R' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Ruby-Fill, the DMEPA safety evaluators also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (eight letters), upstrokes (four, capital letter 'R' and 'F', and lower case 'b', and 'l'), down strokes (one, lower case 'y'), cross strokes (one, lower case 'f'), and dotted letters (one, lower case 'i'). Additionally, several letters in Ruby-Fill may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Ruby-Fill.

When searching to identify potential names that may sound similar to Ruby-Fill, the DMEPA safety evaluators search for names with similar number of syllables (three), stresses (Ru-by and fill), and placement of vowel and consonant sounds. (See Appendix B). The Sponsor's intended pronunciation (Ru-bi-fil) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies. (See Appendix C for samples and results).

2.3 LABEL AND LABELING RISK ASSESSMENT

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The container labels and carton labeling communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the USP-ISMP Medication

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[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.[3]

2.3.1 Adverse Event Reporting System (AERS) Database

The reference listed drug, Cardiogen-82, for the proposed product is currently marketed; therefore, DMEPA conducted a search of the FDA Adverse Event Reporting System (AERS) database to identify any medication errors related to the labels, labeling or packaging of Cardiogen-82 that may also occur with Ruby-Fill. An AERS search was conducted on October 6, 2010 using the trade name "Cardiogen" established name 'Rubidium"and verbatim term "Cardioge%' and 'Rubidiu%" The reactions used were the HLGT term, "Medication Errors," and the PT term, "Product Quality Issue."

The reports were manually reviewed to determine if a medication error occurred. If an error occurred, the staff reviewed the reports to determine if the error could also occur with Ruby-Fill. Those reports that did not describe a medication error or did not describe an error applicable to this review (e.g. errors involving concomitant drugs) were excluded from further analysis. Duplicate reports were combined into cases. The cases that did describe a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors.

2.3.2 Label and Labeling Risk Assessment

The Division of Medication Error Prevention and Analysis (DMEPA) used Failure Mode and Effects Analysis (FMEA) to evaluate the label and labeling submitted as part of the February 26, 2010, submission (Appendices H).

3 RESULTS

3.1 DATA BASE AND INFORMATION SOURCES

The searches yielded a total of 10 names as having some similarity to the name Ruby-Fill.

Five of the names were thought to look like Ruby-Fill. These include: Nulytely, Rapaflo, Rebif, Redisol and Rubesol. The remaining five names were thought to look and sound similar to Ruby-Fill: Rebetol, Robathol, Rubella Virus Vaccine, Robinul, and Rubivite.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 6, 2010.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Ruby-Fill.

[3] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 PRESCRIPTION ANALYSIS STUDIES

A total of 33 practitioners responded to the prescription analyses studies with ten of the participants interpreting the scripted name sample correctly as "Ruby-Fill," with correct interpretation occurring in both of the written studies. However, for practitioners interpreting the written prescription for Ruby-Fill incorrectly, none of the responses overlapped with any existing drug product name. In the verbal studies, two participants understood the spoken proposed name sample correctly as "Ruby-Fill". See Appendix C for the complete listing of interpretations from the verbal and written prescription studies

3.4 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in five additional names which were thought to look or sound similar to Ruby-Fill and represent a potential source of drug name confusion. These names included: Ruby-Fill, Nivigil, Rubywood, Pulzium, and Poly-ICLC.

One name "Ruby-Fill" was not evaluated further since it was identified on the U.S. Patent and Trademark Office website registered for this product. Thus, we evaluated fourteen names: four identified by the primary safety evaluator and 10 identified in Section 3.1 above.

3.5 COMMENTS FROM THE DIVISION OF MEDICAL IMAGING PRODUCTS (DMIP) AND OFFICE OF GENERIC DRUGS (OGD)

3.5.1 Initial Phase of Review

In response to the OSE, July 20, 2010 e-mail, DMIP did not forward any concerns on the proposed name at the initial phase of the name review.

In response to the OSE, July 20, 2010 e-mail, the Office of Generic Drugs (OGD), did not respond with any concerns on the name Ruby-Fill.

3.5.2 Midpoint of Review

DMEPA notified OGD via e-mail that we had no concerns with the proposed proprietary name, Ruby-Fill, on December 01, 2010. Per e-mail correspondence from OGD on December 01, 2010, they indicated the Division had no other issues with the proposed proprietary name, Ruby-Fill.

3.6 LABEL AND LABELING RISK ASSESSMENT

The Division of Medication Error Prevention and Analysis (DMEPA) evaluated the identified medication errors involving the Reference Listed Drug, Cardiogen-82. In addition, our assessment of the container label submitted by the Applicant has identified vulnerabilities that could lead to medication errors.

3.6.1 Adverse Event Reporting System (AERS) Database

The AERS search conducted on October 6, 2010, did not retrieve any cases.

3.6.2 Label and Labeling

Our label and labeling risk assessment identified needed improvement in the following areas:

- Deleting the graphic next to the proprietary name presentation.
- Using a different font color to increase the prominence of the warning and relocating the warning statement to the principal display panel (PDP).

4 DISCUSSION

Ruby-Fill is the proposed proprietary name for Rubidium Rb 82 Generator Injection. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. The Applicant proposes to use the term 'Fill' in their proprietary names for a range of radiopharmaceutical products and aides intended to be used in nuclear medicine. During a teleconference with the Applicant dated December 1, 2010, we discussed our concern with the Applicant's proposal to use the term 'Fill' in future proposed proprietary names for pharmaceutical products. DMEPA informed the Applicant that use of the term 'Fill' may affect the acceptability of future proposed proprietary names and needs to be limited to a single product to avoid confusion within the product line.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA, DMIP and OGD concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

DMEPA evaluated 14 names for their potential similarity to the proposed name, Ruby-Fill. No other aspects of the name were considered to pose potential confusion with the name.

Five of the fourteen names did not undergo failure mode and effect analysis (FMEA) because they were either vitamin supplements not dispensed pursuant to a prescription, discontinued proprietary names for products available under the established name or other proprietary names, or names with limited information (see Appendices D-F).

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining nine names and lead to medication errors. This analysis determined that the name similarity between Ruby-Fill and all of the identified names was unlikely to result in medication error for the reasons presented in Appendices G.

4.3 LABEL AND LABELING RISK ASSESSMENT

The label and labeling risk assessment indicates the presentation of information on the proposed labels and labeling introduces vulnerability to confusion that can lead to medication errors. We identified needed improvement in the following areas: Use of distracting graphic next to the proprietary name presentation and lack of prominence of the warning statement. We provide label and labeling recommendations in section 5 below.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Ruby-Fill, 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, Ruby-Fill, for this product at this time. The Applicant will be notified via letter.

If any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

The proposed labels and labeling risk assessment noted areas of needed improvement in order to minimize the potential for medication errors. We request the recommendations for the container label and carton labeling in Section 5.2 be communicated to the Applicant prior to approval.

Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications on this review, please contact the OSE Regulatory Project Manager, Sandra Griffith, project manager, at 301-796-2445.

5.1 COMMENTS TO THE APPLICANT

5.1.1 Proprietary Name Risk Assessment

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

Ruby-Fill will be re-reviewed 90 days prior to the approval of the ANDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

5.2 COMMENTS TO OFFICE OF GENERIC DRUGS

5.2.1 Label and Labeling Risk Assessment

A. **Container Label**

1. [redacted] (b) (4) The

proprietary name, established name, and strength should be the most prominent information communicated on the principal display panel.

2. Relocate the total activity statement such that it appears below the established name, and above the statement 'Diagnostic agent....use'

3. We recommend that a different color font (such as red) or bolding of letters be utilized for the warning statement that appears on the side panel to increase its prominence and highlight this information.

4. Add the statement 'Generator column must not be removed from lead shield' to the warning.

6 REFERENCES

1. Micromedex Integrated Index (http://csi.micromedex.com)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. Division of Medication Errors Prevention and Analysis proprietary name consultation 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.

6. 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.

7. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. U.S. Patent and Trademark Office (http://www.uspto.gov)

USPTO provides information regarding patent and trademarks.

9. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

10. Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

15. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

16. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [4]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [5] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and

[4] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

[5] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

monitoring the impact of the medication.[6] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication

[6] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare

professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[7] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

[7] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that

could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Sponsor. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Ruby-Fill	Scripted may appear as	Spoken may be interpreted as
Upper case 'R'	B, Pr, n, s	wr
Lower case 'u'	Any vowel	Any vowel
Lower case 'b'	L, k, h	D, P
lower case 'y'	P, f	E, I, u
Upper case 'f'	t	
lower case 'i'	Any vowel	Any vowel
lower case 'l'	b, h, d, s	el

Appendix C: FDA Prescription Study for Ruby-Fill

Figure 1. Ruby-Fill Study Samples (conducted on July 15, 2010)

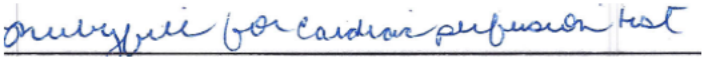
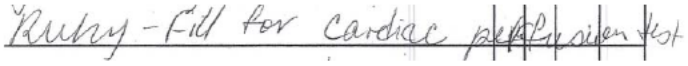
HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order-1 	Ruby-Fill for cardiac perfusion test
Outpatient Rx 	

Table 1: Responses to Prescription Study

Inpatient Medication Order-1	Inpatient Medication Order-2	Voice Prescription
Rubybill	Ruby-Fill	Rubyfill
Orubyfill	Ruby-fill	Rubifil
Onubybill	Ruby-Fill	Rubifill
Prubyfill	Rulry- fill	Rubifil
Orulbyfill?	Ruby - Fill	Rubifell
Prubyfill	Ruby-Fill	Rubifill
Orabyfill	Ruby0Fill	Rubifill
Orubyfill	Ruby-Fill	Rubyfill
Onulybli	Ruby - fill	Rubyfil
Orubyfill	Rutry Fill	Rubifill
	Tuby-Fill	
	Ruby-fill	
	Ruhy Fill	

Appendix D: OTC, nutritional supplement or product not identified as drug and not dispensed pursuant to a prescription.

Proprietary Name	Similarity to Ruby-Fill	Reason
Rubywood	Look	Herbal product (Red sandalwood)
Robathol	Look and sound	Bath oil

Appendix E: Discontinued proprietary names for products available under the established name or other proprietary names.

Proprietary Name	Similarity to Ruby-Fill	Status
Rubivite	Look and sound	Name discontinued, marketed under established name. Preliminary usage data indicates that the product in not prescribed under the name Rubivite.

Appendix F: Names with limited information

Proprietary Name	Similarity to Ruby-Fill	Status
Redisol	Look	Name found in Micromedex. No other information could be obtained from any other pharmaceutical databases.
Rubesol	Look	Name found in Micromedex. No other information could be obtained from any other pharmaceutical databases.

Appendix G : Products with orthographic, phonetic and/or multiple differentiating product characteristics minimize the risk for medication errors.

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Nulytely (Polyethylene Glycol-sodium bicarbonate sodium chloride and potassium chloride) Oral Solution	Look alike	Single strength 420 g-5.72 g-11.2 g- 1.48 g per 4000 mL	240 mL (8 oz) every 10 minutes, until 4 L are consumed	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Ruby-Fill has an additional upstroke 'l' at the end of the name while Nulytely has a additional downstroke 'y' at the end of the name.* Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Route of Administration: *Intravenous infusion using a specific infusion system vs. oral* Dosage Form: *Stannic oxide column encased in lead shield vs. oral solution* Frequency: *One time vs. every 10 minutes, until 4 L are consumed*

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Rapaflo (Silodosin) Capsules	Look alike	4 mg 8 mg	1 capsule once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Ruby-Fill has an additional downstroke 'y' and a additional upstroke 'l' at the end of the name which is absent in Rapaflo* <u>Setting of use:</u> *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* <u>Route of Administration:</u> *Intravenous infusion using a specific infusion system vs. oral* Dose: (b) (4) *mCi vs. one capsule or 4mg, and 8mg* <u>Dosage Form:</u> *Stannic oxide column encased in lead shield vs. capsules* <u>Frequency:</u> *One time vs. once daily*

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Rebif (Interferon beta-1a) Injection Solution	Look alike	8.8 mcg/0.2 mL 22 mcg/0.5 mL 44 mcg/0.5 mL	4.4 mcg to 44 mcg subcutaneously given one to three times weekly.	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Ruby-Fill has a downstroke 'y' and additional upstrokes 'l' at the end of the name which is absent in Rebif* *Ruby-Fill (8 letters) appears longer than Rebif (5 letters) when scripted* Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies* *Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Dosage form: *Stannic oxide column encased in lead shield vs. injection solution* Frequency: *One time vs. one to three times daily* Strength: (b) (4) *millicuries vs. 8.8 mcg/0.2 mL, 22 mcg/0.5 mL and 44 mcg/0.5 mL*

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Rebetol (Ribavirin) Capsules and Oral Solution	Look and sound alike	Capsule: 200 mg Oral Solution: 40 mg/mL	Adults: 400 mg to 600 mg twice daily. Pediatrics: 15 mg/kg/day in 2 divided doses or 200 to 400 mg	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Ruby-Fill has an additional downstroke 'y' and a additional upstroke 'l' at the end of the name which is absent in Rebetol* Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Route of Administration: *Intravenous infusion using a specific infusion system vs. oral* Dosage Form: *Stannic oxide column encased in lead shield vs. capsules or oral solution* Frequency: *One time vs. twice daily*

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Rubella Virus Vaccine powder for Injection	Look and sound alike	Single strength 1000 units/vial	Inject 0.5 mL subcutaneously once	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Ruby-Fill has an additional downstroke 'y' which is absent in Rubella virus vaccine* *Rubella virus vaccine (3 words) appears longer than Ruby-Fill when scripted.* <u>Setting of use:</u> *Nuclear pharmacy vs. inpatient or outpatient pharmacies* *Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* <u>Dosage form</u> *Stannic oxide column encased in lead shield vs. injection solution* Dose: (b) (4) *mCi vs. 0.5 mL*

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Robinul (Glycopyrrolate) Tablets and Injection Solution	Look and sound alike	Single strength Tablets: 1 mg Injection Solution: 0.2 mg/mL	Adults: Oral: 1 mg to 2 mg 2-3 times/day Intramuscular or Intravenous: 0.1 mg -0.2 mg 3-4 times/day. Pediatrics: Oral: 40 -100 mcg/kg/dose 3-4 times/day Intramuscular or Intravenous: 4-10 mcg/kg/dose every 3-4 hours	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Ruby-Fill has an additional downstroke 'y' and a additional upstroke 'f' and 'l' in the name which is absent in Robinul.* Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Frequency: *One time vs. 2 to 4 times daily* Dosage form *Stannic oxide column encased in lead shield vs. injection solution*
Nuvigil (Armodafinil) Tablets	Sound alike	50 mg 150 mg 250 mg	150 mg -250 mg once daily	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Route of Administration: *Intravenous infusion using a specific infusion system vs. oral* Dosage Form: *Stannic oxide column encased in lead shield vs. tablets* Frequency: *One time vs. once daily*

Product name with potential for confusion	Similarity to Ruby-Fill	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Ruby-Fill (Rubidium Rb 82 Generator) Injection Solution	**N/A**	(b) (4) **millicuries of strontium SR-82**	(b) (4)	**N/A**
Pulzium (Tedisamil) Injection Solution	Look alike	Single strength 20 mg/10 mL	0.48 mg/kg for males and 0.32 mg/kg for females through intravenous injection once	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Ruby-Fill has additional upstrokes 'f' and 'l' at the end of the name which is absent in Pulzium* Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Dosage Form: *Stannic oxide column encased in lead shield vs. injection solution*
Poly-ICLC Injection Solution	Look alike	Single strength 2 mg/mL	10 to 30 mcg/kg given subcutaneously one to three times weekly	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Ruby-Fill has a upstroke 'f' which introduces a downstroke in that position and is absent in Poly-ICLC* Setting of use: *Nuclear pharmacy vs. inpatient or outpatient pharmacies Nuclear medications are ordered, procured, and dispensed pursuant to the regulations by U.S. Nuclear Regulatory Commission.* Dosage Form: *Stannic oxide column encased in lead shield vs. injection solution* Frequency: *One time vs. one to three times weekly*

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/s/

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