CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022454Orig1s000

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

Application Type/Number:	NDA# 022454
Date:	January 4, 2011
Through:	Todd Bridges, RPh, Team Leader Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Denise V. Baugh, PharmD, BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Datscan (Ioflupane I 123) Injection
Applicant:	GE Healthcare
OSE RCM #:	2010-2658

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

1 INTRODUCTION

This re-assessment of the proprietary name, Datscan is in anticipation of the approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Datscan, acceptable in OSE Review #2009-744, dated June 29, 2009 and OSE Review # 2009-2285, dated December 14, 2009. The Division of Medical Imaging Products did not have any concerns with the proposed name, Datscan, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on May 7, 2009.

2 METHODS AND RESULTS

For the final review of the proposed proprietary name, Datscan, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review# 2009-744 and OSE Review# 2009-2285. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases referenced in Section 4.2 did not yield any new names thought to look or sound similar to Datscan and represent a potential source of drug name confusion.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Datscan, as of January 2, 2011.

3 CONCLUSIONS AND RECOMMENDATIONS

The proprietary name risk assessment findings indicate that the proposed name, Datscan, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Datscan, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Medical Imaging Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

4.1 REVIEWS

1. Baugh, D. OSE Review # 2009-744, Proprietary Name Review for Datscan. June 29, 2009.
2. Baugh, D. OSE Review # 2009-2285, Proprietary Name Review of Datscan. December 14, 2009.

4.2 DATABASES

1. 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.

2. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)

USAN Stems List contains all the recognized USAN stems.

3. CDER Proposed Names List

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

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/s/

DENISE V BAUGH
01/04/2011

TODD D BRIDGES
01/04/2011

DENISE P TOYER
01/05/2011

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 14, 2009
To:	Rafel Dwaine Rieves, MD, Acting Director Division of Medical Imaging and Hematology Products
Through:	Todd Bridges, RPh, Team Leader Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Denise V. Baugh, PharmD, BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	DaTscan (Ioflupane I 123) Injection
Application Type/Number:	NDA# 022454
Applicant:	GE Healthcare
OSE RCM #:	2009-2285

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CONTENTS

1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, DaTscan, acceptable in OSE Review #2009-744, dated June 29, 2009. The Division of Medical Imaging and Hematology Products did not have any concerns with the proposed name, DaTscan, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on May 7, 2009.

2 METHODS AND RESULTS

For the final review of the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review #2009-744 and since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases referenced in Section 4.2 did not yield any new names thought to look or sound similar to DaTscan and represent a potential source of drug name confusion.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, DaTscan, as of December 7, 2009.

3 CONCLUSIONS AND RECOMMENDATIONS

The proprietary name risk assessment findings indicate that the proposed name, Datscan, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, DaTscan, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Medical Imaging and Hematology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

4.1 REVIEW

1. OSE Review # 2009-744, Proprietary Name Review of DaTSCAN; Baugh, D., Safety Evaluator.

4.2 DATABASES

1. 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.

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22454	ORIG-1	GE HEALTHCARE INC	DA TSCAN

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/s/

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12/14/2009

TODD D BRIDGES
12/14/2009

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12/14/2009

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:	June 29, 2009
To:	Rafel Dwaine Rieves, MD, Acting Director Division of Medical Imaging and Hematology Products
Through:	Todd Bridges, RPh, Team Leader Denise P. Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Denise V. Baugh, PharmD, BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	DaTSCAN (Ioflupane I 123) Injection
Application Type/Number:	NDA# 22-454
Applicant:	GE Healthcare
OSE RCM #:	2009-744

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CONTENTS

EXECUTIVE SUMMARY

DaTSCAN is the proposed proprietary name for Ioflupane I 123 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. Our review noted the use of tall man lettering in the proposed proprietary name, 'DatSCAN'. Presenting the '-TSCAN' portion of the name in capital letters is consistent with lettering which is typically reserved for differentiating known look-alike established name pairs or in rare circumstances for proprietary name pairs to help reduce the risk of name confusion resulting in medication error. Since 'DaTSCAN' is not a name that has been involved in name confusion the capitalization of the letters '-TSCAN' is inappropriately applied. Thus, DMEPA finds the proposed proprietary name DaTSCAN acceptable provided the "TSCAN" portion of the name is presented in lower case letters. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

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.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from GE Healthcare dated April 16, 2009, for an assessment of the proposed proprietary name, DaTSCAN, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. Labels and labeling were submitted separately and will be reviewed under OSE# 2009-842.

1.2 PRODUCT INFORMATION

DaTSCAN (Ioflupane I 123) Injection is a radiopharmaceutical indicated for detecting loss of functional nigrostriatal dopaminergic neurons by single photon emission computed tomography (SPECT) imaging in patients presenting with symptoms or signs suggestive of dopaminergic neurodegeneration. DaTSCAN emits gamma radiation and must be handled with appropriate safety measures. The recommended dose for adults is 111 MBq to 185 MBq (3 mCi to 5 mCi). The dose is measured by a suitable radioactivity calibration system immediately prior to administration. DaTSCAN is supplied as a sterile solution for intravenous injection in a single dose vial containing 2.5 mL [74 MBq (2 mCi)/mL at calibration time].

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, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, DaTSCAN.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'D' 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 DaTSCAN, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Furthermore, we acknowledge that the Applicant presents the name in capital letters with the exception of the first letter 'a'. The rationale presented was to avoid confusion with the acronym for 'Dementia of the Alzheimer Type'. However, the letters 'TSCAN' in DaTSCAN may not always be capitalized by the writer when scripted. As such, DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to DaTSCAN. Specific attributes taken into consideration include the length of the name (seven), upstrokes (two, 'D' and lower case 't'), down strokes (none), cross strokes (one, lower case 't'), and dotted letters (none). Additionally, several letters in DaTSCAN may be vulnerable to ambiguity when scripted, including the letter 'D' may appear as 'O' or 'Q'; lower case 'a' may appear as lower case 'c', or the combination letters '-ci-', '-ce-', or '-el-' while an upper case 'A' may appear as an upper case 'O' or 'Q'; lower case 't' may appear as a lower case 'x' or 'f' while upper case 'T' may appear as a 'Z' or 'F'; lower case 's' may appear as a lower case 'g' while an upper case 'S' may appear as an upper case 'J' or 'G'; lower case 'c' may appear as lower case 'a' and vice versa whereas an upper case 'C' may appear as an upper case 'L'; lower case 'n' may appear as a lower case 'r', 'u', 'x', 'h' or 's' whereas an upper case 'N' may appear as an upper case 'V'.

When searching to identify potential names that may sound similar to DaTSCAN, the DMEPA staff searches for names with similar number of syllables (two), stresses (DAT-scan, dat-SCAN), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary. Furthermore, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

DMEPA also considered the Applicant's intended pronunciation of the proprietary name, dat-skan, as it was provided in the submission.

2.2 FDA 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 were communicated during the FDA prescription studies.

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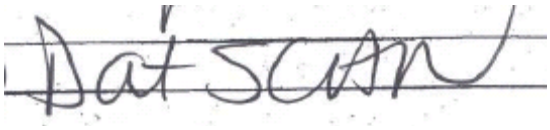
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

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

Figure 1. DaTSCAN Prescription Study (conducted on May 20, 2009)

HANDWRITTEN MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: 	"Datscan"
Outpatient Prescription: 	

2.3 ADVERSE EVENT REPORTING SYSTEM (AERS) SEARCH

Since DaTSCAN is currently marketed outside of the U.S., an AERS search was done on April 29, 2009, using the trade name "DaTSCAN", "Da TSCAN" and the active ingredient "Ioflupane I 123". The MedDRA High Level Group Term (HLGT), "medication errors" and the Preferred Term (PT), "pharmaceutical product complaint" were also used in the search.

The cases were manually reviewed to determine if a medication error occurred. Those cases that did not describe a medication error were excluded from further analysis. The cases that did describe a medication error were categorized by type of error. Our Division reviewed the cases within each category to identify factors that contributed to the medication errors, and to ascertain if these risks might apply to the proposed product, DaTSCAN.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of fifteen names as having some similarity to the proposed proprietary name, DaTSCAN.

Twelve of the names were thought to look like DaTSCAN. These include Lexiscan, Detane, Claforan, Ditropan, Dantrium, Daytrana, Octreoscan, Selsun, Patanase, Pitocin, Dutramen (b) (4). The remaining three names were thought to look and sound similar to DaTSCAN: Datscan, Datisan and Dextran.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 14, 2009.

3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted one additional name thought to have phonetic similarity to DaTSCAN ('cat'scan, the acronym for computed axial tomography, sometimes abbreviated as CT scan).

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 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 21 practitioners responded but none of the responses overlapped with any existing or proposed drug names. Seventeen of the participants interpreted the name correctly as "DaTSCAN," with correct interpretation occurring in all studies: inpatient written study (n=11), the outpatient written study (n=4), and the verbal study (n = 2). The remainder of the written responses misinterpreted the drug name. In the verbal studies, one of the responses was a misspelled phonetic variation of the proposed name, DaTSCAN. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.4 COMMENTS FROM THE DIVISION OF MEDICAL IMAGING AND HEMATOLOGY PRODUCTS

In response to the OSE May 29, 2009, e-mail, the Division of Medical Imaging and Hematology Products did not have any objections to the proposed name at the initial phase of the name review.

DMEPA notified the Division of Medical Imaging and Hematology Products via e-mail that we had no objections to the proposed proprietary name, DaTSCAN, on June 16, 2009. Per e-mail correspondence from the Division of Medical Imaging and Hematology Products on June 24, 2009, they indicated they concur with our assessment of the proposed proprietary name, DaTSCAN.

3.5 AERS SELECTION OF CASES

Our search of AERS did not identify any medication errors associated with DaTSCAN as of April 29, 2009.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in no additional names which were thought to look or sound similar to DaTSCAN and represent a potential source of drug name confusion.

4 DISCUSSION

Neither DDMAC nor the Division had concerns with the proposed proprietary name. DMEPA identified and evaluated sixteen names for their potential similarity to the proposed name, DaTSCAN. One name identified, DaTSCAN, was found to be the subject of this review and was eliminated. The results of our proprietary name risk assessment found that the proposed name is not vulnerable to name confusion that could lead to medication errors with any of the fifteen names for the reasons presented in Appendices C through H.

Additionally, DMEPA noted the applicant is proposing to use tall-man lettering '-TSCAN' in the proposed name DaTSCAN. The use of lower case and capital letters in the name is an example of tall-man lettering. Tall-man lettering is generally reserved for distinguishing specific portions of established names that are similar in order to differentiate known look-alike names that have been confused and resulted in medication errors. Thus, the use of tall-man letters in the proposed proprietary name "DaTSCAN" is inappropriate and should not be used.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, DaTSCAN, is acceptable if it is presented without tall man lettering. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, DaTSCAN, on the condition that the last five letters, '-TSCAN' be presented in lower case letters.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation. If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

5.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, DaTSCAN, and have concluded that it is acceptable provided the '-TSCAN' portion of the name is presented in lower case letters so it reads 'Datscan' on all labels and labeling.

Presenting the '-TSCAN' portion of the name in capital letters is consistent with lettering which is typically reserved for differentiating known look-alike established name pairs or in rare circumstances for proprietary name pairs to help reduce the risk of name confusion resulting in medication error. Since 'DaTSCAN' is not a name that has been involved in name confusion the capitalization of the letters "TSCAN" is inappropriately applied.

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

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. AMF Decision Support System [DSS]

DSS is a government database used to track individual submissions and assignments in 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/category/4782.html)

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. [3]

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

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

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. [4] 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 monitoring the impact of the medication.[5] 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 Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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

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

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
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 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 Office of 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.[6] 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.

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:

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

"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 Applicant 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 Applicant 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 Applicant. 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), Joint Commission on Accreditation of Hospitals (JCOAH), 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 Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant 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 Applicants' 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.

Appendix B: FDA Prescription Study Responses (completed May 20, 2009)

Inpatient Medication Order	Outpatient Medication Order	Voice Prescription
Datscan	DatScan	Dat Scan
Datsuan	DatSCAN	Dapscan
Dat Scan	Datscan	Dat Scan
DatSCAN	DatScan	
DatSCAN	Dat Scan	
	Datscar	
	DatScrin	
	DatScan	
	Datscan	
	DatScan	
	DatScan	
	DatScan	
	Datscan	

Appendix C: Names Lacking Orthographic and/or Phonetic Similarity.

Name	Similarity to DaTSCAN
Lexiscan	Look
Octreoscan	Look
Selsun	Look
Daytrana	Look

Appendix D: Proprietary Name used only in a Foreign Country

Proprietary Name	Similarity to DaTSCAN	Country
Datisan (mitomycin)	Sound and Look	Argentina

Appendix E: Products withdrawn from the market and no generic equivalent products currently available

Proprietary Name	Similarity to DaTSCAN	Status and Date
(b) (4)	Look	NDA withdrawn by Applicant in 1983

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

Appendix F: Products with no numerical overlap in strength and dose

Product name with potential for confusion	Similarity to DaTSCAN	Strength	Usual Dose
DaTSCAN	**N/A**	**74 MBq (2 mCi)/mL**	**111 MBq to 185 MBq (3 mCi to 5 mCi) as single intravenous administration**
Ditropan (oxybutynin)	Look	5 mg, 10 mg, 15 mg	5 mg to 30 mg orally once daily
Dantrium (dantrolene)	Look	25 mg, 50 mg, 100 mg	Begin with 25 mg orally once daily for 7 days with a final dosage of 100 mg orally 3 times daily if necessary
Dextran for Injection	Sound and Look	40, 70, 75	500 mL to 1000 mL given at a rate of 20 mL to 40 mL/minute in an emergency
Claforan (cefotaxime) for Injection	Look	500 mg, 1 g, 2 g, 10 g	1 g to 2 g intravenous/intramuscularly every 8 hours

Appendix G: Single strength products with multiple differentiating product characteristics

Product name with potential for confusion	**Similarity to DaTSCAN**	**Strength**	**Usual Dose (if applicable)**	**Differentiating Product Characteristics (DaTSCAN vs. Product)**
DaTSCAN	**N/A**	**74 MBq (2 mCi) per mL**	**111 MBq to 185 MBq (3 mCi to 5 mCi)**	**Dose - 111 to 185 MBq (3 mCi to 5 mCi)** **Dosage Form – solution** **Units of Measure - MBq or mCi** **Route of Administration intravenous** **Frequency of Administration once**
Detane (benzocaine) topical gel	Look	7.5%	2.5 grams over 20 cm^2 to 25 cm^2 of skin surface or 1 anesthetic disc for at least 1 to 2 hours depending upon the procedure	Dose – 2.5 grams Dosage form - gel Route of administration – topical
Patanase (olopatadine) intranasal spray solution	Look	0.6%	Two sprays per nostril twice daily	Dose – two sprays Dosage form – spray Route of administration – nasal Frequency of administration – twice daily
Pitocin (Oxytocin) injection	Look	10 units per mL	Up to 0.5 to 2 milliunits/minute for induction or stimulation of labor	Dose – 0.5 milliunits to 2 milliunits Frequency of administration – continuous infusion
Dutramen*** (Toremifene) Tablets	Look	80 mg	One tablet orally daily	Dose – 80 mg Dosage form – tablet Route of administration – oral Frequency of administration – once daily

Appendix H: Potential confusing name which is not a drug name

Failure Mode: Name confusion	**Causes (could be multiple)**	**Rationale why medication error is unlikely to occur in the usual practice setting.**
Proprietary Name	**Strength**	**Usual Dose:**
DaTSCAN	**74 MBq (2 mCi)/mL**	**111 MBq to 185 MBq (3 mCi to 5 mCi)**
Cat Scan (sometimes abbreviated as CT scan)	Names sound similar because their prefixes are not distinguishable when spoken (‘Dat-‘ vs. ‘Cat-‘) and because of their shared suffix (‘scan’). Both names are associated with the imaging practice setting and are used to diagnose a condition.	The requirements for submitting a complete order are different. For example, when giving a telephone order for a ‘cat’ scan, the prescriber is required to provide a diagnosis and/or area of the body to be scanned. For DaTSCAN, the prescriber would have to provide a dose to complete the order. These different criteria would help prevent confusion between a ‘cat’ scan and DaTSCAN.

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