CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210656Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	July 17, 2018
Application Type and Number:	NDA 210656
Product Name and Strength:	Daurismo (glasdegib) tablet 25 mg and 100 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer
Panorama #:	2018-22736170
DMEPA Safety Evaluator:	Idalia E. Rychlik, PharmD.
DMEPA Team Leader:	Hina Mehta, PharmD.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Daurismo, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A, respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 30, 2018.

- Intended Pronunciation: DOOR' is-moe
- Active Ingredient: glasdegib
- Indication of Use: [redacted] (b) (4)
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 25 mg and 100 mg
- Dose and Frequency: 1 tablet (100 mg) once daily; dose adjusted for toxicity to 50 mg (2 tablets) and/or held and/or discontinued.
- How Supplied: 30-count bottle for the 100 mg and 60-count bottle for the 25 mg
- Storage: Store at 20 C to 25 C (68 F to 77 F); excursions permitted between 15oC to 30 C (59 F to 86 F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Daurismo in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 10, 2018 e-mail, the Division of Hematology Products (DHP) did have concerns relating to the proposed proprietary name at the initial phase of the review. In an email communication dated May 11, 2018, the clinical review team expressed their concern that the proprietary name, Daurismo can be confused with the established name daunorubicin. The clinical team is concerned because both agents start with the identical 3-letter string 'Dau-'and are both considered "front-line AML drugs", which may render them vulnerable to possible name confusion and medication errors. We carefully considered the Division's concern and further evaluated the risk of confusion between Daurismo and daunorubicin as follows:

Orthographic and Phonetic Differences:
In evaluating the proposed proprietary name Daurismo and the currently marketed product daunorubicin, we note the infix/suffix letter strings "ismo" vs. "orubicin" of the name pair have sufficient orthographic differences, and give the names a different length and shape. Phonetically, the second ("is" vs. "o") and third ("mo" vs. "rubi") syllables of the name pair have sufficient differences and daunorubicin contains an extra 2 syllables. Furthermore, FDA's Phonetic and Orthographic Computer Analysis (POCA) software calculates a 50% combined orthographic and phonetic score for the name pair, indicating low similarity.[b]

Product Characteristic differences:
We note that daunorubicin, a cytotoxic agent approved in 1998, is indicated for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults, in combination with other approved anticancer drugs. Daurismo is a hedgehog pathway inhibitor (b) (4) However, the products have different strengths, dosage forms and route of administration (see Table below) which reduces the risk for the confusion between the two names. We note there is a potential for toxicity-induced dose reductions to overlap at the 50 mg dose, however the dosing schedule provides some error mitigation (see Table below).

[a] USAN stem search conducted on 5/14/2018

[b] POCA search conducted on May 15, 2018 in version 4.2.

Product Characteristics	Daurismo	daunorubicin
Active ingredient	glasdegib	daunorubicin
Indication	(b) (4)	In combination with other approved anticancer drugs for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults.
Dosage Form	Tablets	Injection
Strength	25 mg, 100 mg	5 mg/mL
Route	Oral	Intravenous infusion
Dose and frequency	1 tablet (100 mg) daily Dose adjusted for toxicity to 50 mg (2 tablets) and/or held and/or discontinued.	**Representative Dose Schedules and Combination for the Approved Indication of Remission Induction in Adult Acute Nonlymphocytic Leukemia** For patients under age 60, daunorubicin hydrochloride 45 mg/m^2/day IV on days 1, 2, and 3 of the first course and on days 1, 2 of subsequent courses AND cytosine arabinoside 100 mg/m^2/day IV infusion daily for 7 days for the first course and for 5 days for subsequent courses. For patients 60 years of age and above, daunorubicin hydrochloride 30 mg/m^2/day IV on days 1, 2, and 3 of the first course and on days 1, 2 of subsequent courses AND cytosine arabinoside 100 mg/m^2/day IV infusion daily for 7 days for the first course and for 5 days for subsequent courses. This daunorubicin hydrochloride dose-reduction is based on a single study and may not be appropriate if optimal supportive care is available. **Representative Dose Schedule and Combination for the Approved Indication of Remission Induction in Pediatric Acute Lymphocytic Leukemia**

Product Characteristics	Daurismo	daunorubicin
		Daunorubicin hydrochloride 25 mg/m^2 IV on day 1 every week, vincristine 1.5 mg/m^2 IV on day 1 every week, prednisone 40 mg/m^2 PO daily. Generally, a complete remission will be obtained within four such courses of therapy; however, if after four courses the patient is in partial remission, an additional one or, if necessary, two courses may be given in an effort to obtain a complete remission. In children less than 2 years of age or below 0.5 m^2 body surface area, it has been recommended that the daunorubicin hydrochloride dosage calculation should be based on weight (1 mg/kg) instead of body surface area. **Representative Dose Schedules and Combination for the Approved Indication of Remission Induction in Adult Acute Lymphocytic Leukemia** Daunorubicin hydrochloride 45 mg/m^2/day IV on days 1, 2, and 3 AND vincristine 2 mg IV on days 1, 8, and 15; prednisone 40 mg/m^2/day PO on days 1 through 22, then tapered between days 22 to 29; L-asparaginase 500 IU/kg/day X 10 days IV on days 22 through 32.

In addition, we find that any residual risk of name confusion is further mitigated by the well-differentiated labels and labeling, which may further reduce the risk of a medication error reaching the patient.

In summary, we find that when considered in totality, these mitigations minimize the likelihood of name confusion between Daurismo and daunorubicin in the clinical setting.

2.2.4 FDA Name Simulation Studies

Fifty-eight (58) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search[c] identified 63 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 *Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA search and a name of concern identified by the Division of Hematology Products. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	56
Low similarity name pair: combined match percentage score ≤54%	6

2.2.7 *Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities*

Our analysis of the 64 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on July 10, 2018. At that time we also requested additional information or concerns that could inform our review. The Division did not submit additional concerns with the proposed proprietary name, Daurismo.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

[c] POCA search conducted on 5/14/2018 in version 4.2.

If any of the proposed product characteristics as stated in your submission, received on April 30, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***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.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. 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. [d]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   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 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 record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for 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 OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/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 provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Daurismo Study (Conducted on 5/18/2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Daurismo 50 mg by mouth daily Outpatient Prescription: Daurismo 1 tablet (100 mg) by mouth daily 30	Daurismo Take 1 tablet (100 mg) by mouth daily. #30

FDA Prescription Simulation Responses (Aggregate Rx Studies Report)

308 People Received Study
58 People Responded

Study Name: Daurismo

Total	19	19	20	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CUARISMO	1	0	0	1
DANRISMO	1	0	0	1
DAURISMA	1	0	0	1
DAURISMO	15	0	19	34
DAVRISMO	1	0	0	1
DORESMO	0	1	0	1
DORISMO	0	8	0	8
DORIZMO	0	5	0	5
DORYSMO	0	2	0	2
DORYTHMO	0	1	0	1
DURISMO	0	1	1	2
DURYZMO	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name: Daurismo Established name: glasdegib Dosage form: tablet Strength(s): 25 mg, 100 mg Usual Dose: 100 mg (1 tablet) once daily; dose adjustment due to toxicity to 50 mg (2 tablets) once daily or dose held/discontinued**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Daurismo	100	Subject of this review.
2.	Carisoma	70	International product marketed in India and formerly marketed in UK.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Drisdol	66
2.	Duration	61
3.	Diurex Max	57
4.	Durasal	57
5.	Darcalma	57
6.	Iduridin	56
7.	Duradrin	55
8.	Vaprisol	55

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Daurismo Established name: glasdegib Dosage form: tablet Strength(s): 25 mg, 100 mg Usual Dose: 100 mg (1 tablet) once daily; dose adjustment due to toxicity to 50 mg (2 tablets) once daily or dose held/discontinued**	**POCA Score (%)**	**Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	(b) (4)***	64	This name pair has sufficient orthographic and phonetic differences.
2.	Tagrisso	63	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Daurismo Established name: glasdegib Dosage form: tablet Strength(s): 25 mg, 100 mg Usual Dose: 100 mg (1 tablet) once daily; dose adjustment due to toxicity to 50 mg (2 tablets) once daily or dose held/discontinued	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	Daliresp	61	This name pair has sufficient orthographic and phonetic differences.
4.	Daraprim	61	This name pair has sufficient orthographic and phonetic differences.
5.	Diuril Sodium	60	This name pair has sufficient orthographic and phonetic differences.
6.	Duramorph	60	This name pair has sufficient orthographic and phonetic differences.
7.	Myorisan	60	This name pair has sufficient orthographic and phonetic differences.
8.	Apriso	56	This name pair has sufficient orthographic and phonetic differences.
9.	Dristan	56	This name pair has sufficient orthographic and phonetic differences.
10.	Duraflor	56	This name pair has sufficient orthographic and phonetic differences.
11.	Duromorph	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Daurismo Established name: glasdegib Dosage form: tablet Strength(s): 25 mg, 100 mg Usual Dose: 100 mg (1 tablet) once daily; dose adjustment due to toxicity to 50 mg (2 tablets) once daily or dose held/discontinued	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	Daunorubicin	50	We note the infix/suffix letter strings "ismo" vs. "orubicin" of the name pair have sufficient orthographic differences, and give the names a different length and shape. Phonetically, the second ("is" vs. "o") and third ("mo" vs. "rubi") syllables of the name pair have sufficient differences and daunorubicin contains an extra 2 syllables. Differences in Product Characteristics Daurismo vs. Daunorubicin: Dosage form: tablets vs. injection Strength: 25 mg and 100 mg vs. 5 mg/mL Route: oral vs. intravenous infusion Frequency: daily vs. depending on indication: days 1, 2, and 3 of the first course of chemotherapy and on days 1, 2 of subsequent courses. On day 1 of chemotherapy regime every week. On days 1, 2, and 3 of chemotherapy regime.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	auro-Dri	50
2.	Midostaurin	49

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

No.	Name	POCA Score (%)	Failure preventions
1.	Daricon	62	International product marketed in Hong Kong.

No.	Name	POCA Score (%)	Failure preventions
2.	Diuresal	62	International product formerly marketed in Switzerland.
3.	Sarisol No. 1	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Sarisol No. 2	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Drituss Dm	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Duratuss Dm	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Sarisol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Tearisol	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	Duraxin	59	International product formerly marketed in Puerto Rico.
10.	(b) (4) ***	58	Proposed proprietary name for IND 115732 found to be unacceptable (OSE# 2015-2318722). Newly proposed name, Hyrimoz*** for IND 115732 tentatively approved under OSE# 2016-12239481.
11.	Diupres	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Diupres-250	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Diupres-500	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Diurese	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
15.	Duratuss Da	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Fluriso	58	Veterinary product.
17.	Diosmin	56	This is not a drug, it is a medical food product.
18.	Duratuss	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	Muripsin	56	International product marketed in the United Kingdom.
20.	Disobrom	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
21.	Dura Ron	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
22.	Dura-Dumone	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
23.	Duromine	55	International product marketed in new Zealand, Australia, Hong Kong, Malaysia, Philippines and South Africa.
24.	Doxacurium	52	International product formerly marketed in Canada.
25.	Aqua Maris	50	International product marketed in Russia.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f].

No.	Name	POCA Score (%)
1.	Tri-Sudo	62
2.	Touro Dm	60
3.	Baridium	59
4.	(b) (4) ***	58
5.	Normison	58
6.	Samarium Sm153	58
7.	Tarsum	58
8.	Bicarsim	56
9.	Guai Sudo	56
10.	Karidium	56
11.	Parsidol	56
12.	Tri-Pseudo	56
13.	(b) (4) ***	55
14.	Neoasma	55
15.	Midamor	49

[f] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

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07/17/2018

HINA S MEHTA
07/18/2018