CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212904Orig1s000

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:	June 19, 2020
Application Type and Number:	NDA 212904
Product Name and Strength:	Fotivda (tivozanib) capsules, 1 mg and 1.5 mg[c]
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Aveo Pharmaceuticals, Inc. (Aveo)
Panorama #:	2020-38911237
DMEPA Safety Evaluator:	Tingting Gao
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Fotivda, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Aveo submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Aveo previously submitted the proposed proprietary name, Fotivda, on April 4, 2013 for tivozanib capsules under NDA 204408.[a] However, NDA 204408 received a Complete Response on June 6, 2013. Therefore, Aveo withdrew the request for Proprietary Name Review of Fotivda on June 17, 2013.[b] We did not complete a Proprietary Name Review for Fotivda for NDA 204408.

Now, Aveo submitted the name, Fotivda, for review under NDA 212904 on April 1, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 1, 2020. Furthermore, Aveo stated that Fotivda (tivozanib) is approved and commercially available in the European Union and New Zealand.

- Intended Pronunciation: foh-tiv-dah
- Active Ingredient: tivozanib
- Indication of Use: Relapsed or Refractory Renal Cell Carcinoma (RCC)
- Route of Administration: Oral
- Dosage Form: capsules
- Strength: 1 mg and 1.5 mg[c]

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[a] NDA 204408 (tivozanib hydrochloride; AV-951); Sequence #0038. Request for Proprietary Name Review (Fotivda). Cambridge (MA): AVEO Pharmaceuticals, Inc. 2013 April 4. Available from: \\cdsesub1\evsprod\nda204408\0038\m1\us\12-cov-let\cover.pdf.

[b] NDA 204408 (tivozanib hydrochloride; AV-951); Sequence #0044. Product Correspondence: Withdrawal of Request for Proprietary Name Review (Fotivda). Cambridge (MA): AVEO Pharmaceuticals, Inc. 2013 June 17. Available from: \\cdsesub1\evsprod\nda204408\0044\m1\us\12-cov-let\cover.pdf.

[c] The Chemistry, Manufacturing, and Controls (CMC) stated that the drug product name and strength are expressed as salt equivalent (tivozanib hydrochloride) and not as active moiety (tivozanib), and requested Aveo to revise the NDA with expression of strength as active moiety. Aveo proposed new strengths of 0.89 mg and 1.34 mg tivozanib (equivalent to 1.0 mg and 1.5 mg tivozanib hydrochloride) on June 4, 2020 (\\cdsesub1\evsprod\nda212904\0008\m1\us\quality.pdf). Thus, we also considered the strengths 0.89 mg and 1.34 mg in this proprietary name review for Fotivda.

- Dose and Frequency: 1.5 mg once daily with or without food for 21-days on treatment followed by 7 days off treatment (28-day cycle)
    - For moderate hepatic impairment (Child-Pugh B), dose with one 1 mg capsule taken orally once daily for 21 days on treatment followed by 7 days off treatment for a 28-day cycle.
- How Supplied: Bottle of 21 capsules
- Storage: Store at 20°C to 25°C (68°F to 77°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Fotivda would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Fotivda.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Fotivda.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Aveo indicated in their submission that the proposed proprietary name, Fotivda, incorporates elements from the nonproprietary name. 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, April 13, 2020 e-mail, the Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Fotivda at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-nine practitioners participated in DMEPA's prescription studies for Fotivda. 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 prescription simulation studies.

[d] USAN stem search conducted on April 9, 2020.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 43 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 (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	44
Low similarity name pair: combined match percentage score ≤54%	17

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

Our analysis of the 62 names contained in Table 1 determined none of the names will pose a risk for confusion with Fotivda 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 Oncology 1 (DO1) via e-mail on June 17, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 1 (DO1) on June 19, 2020, they stated no additional concerns with the proposed proprietary name, Fotivda.

3 CONCLUSION

The proposed proprietary name, Fotivda, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO AVEO PHARMACEUTICALS, INC.

[e] POCA search conducted on April 9, 2020 in version 4.3.

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

If any of the proposed product characteristics as stated in your submission, received on April 1, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

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. [f]

[f] 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[g]. 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.

[g] 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.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

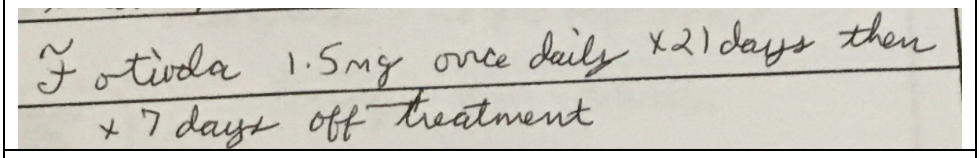
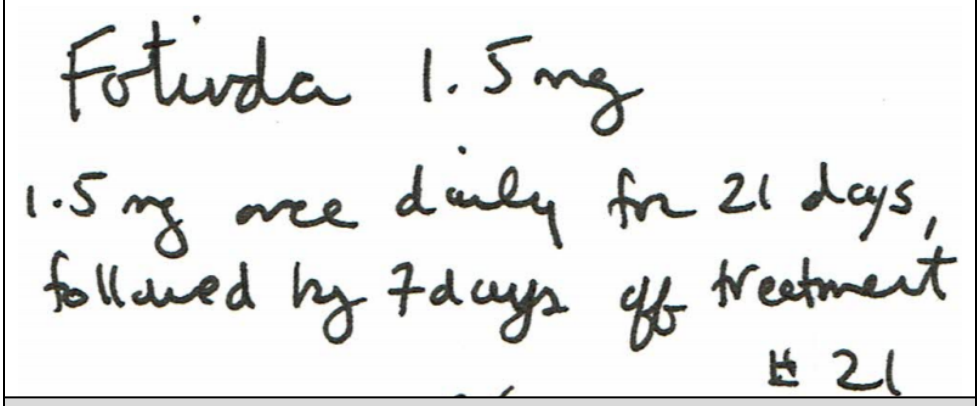
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Fotivda Study (Conducted on April 10, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Fotivda	Fotivda 1.5 mg Take 1.5 mg once daily for 21 days, followed by 7 days off treatment Dispense twenty-one

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Fotivda

209 People Received Study

89 People Responded

Total	34	16	16	23	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
FORTIVDA	2	0	0	4	6
FOTINDA	1	0	0	0	1
FOTIODA	0	0	0	1	1
FOTIRDA	1	0	0	0	1
FOTIVDA	28	16	4	18	66
FOTIVDA 1.5 MG	1	0	0	0	1
FOTUDA	1	0	0	0	1
HOTISDA	0	0	1	0	1
HOTIVDA	0	0	1	0	1
OTIDA	0	0	1	0	1
OTIZA	0	0	1	0	1
POTISDA	0	0	1	0	1
POTIVDA	0	0	2	0	2
PROTIDA	0	0	1	0	1
SOTISZA	0	0	1	0	1
VOTIDA ???	0	0	1	0	1
VOTIDDA	0	0	1	0	1
VOTITA	0	0	1	0	1

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

No.	**Proposed name:** Fotivda **Established name:** tivozanib **Dosage form:** capsules **Strength(s):** 1 mg and 1.5 mg **Usual Dose:** 1.5 mg once daily for 21 days	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.	Fotivda	100	Name is the subject of this review.

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 (%)
2.	Certiva	60
3.	Fetzima	61
4.	Fiv-Asa	56
5.	Folivane-F	56
6.	Foltabs	58
7.	Forfivo	60
8.	Fortabs	58
9.	Fototar	62
10.	Noctiva	62
11.	Optivar	58
12.	(b) (4)***	57
13.	Potiga	63
14.	Stivarga	58
15.	Sustiva	62
16.	Tris-EDTA	55
17.	Zontivity	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:** Fotivda **Established name:** tivozanib **Dosage form:** capsules **Strength(s):** 1 mg and 1.5 mg **Usual Dose:** 1.5 mg once daily for 21 days	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**
18.	Ativan	56	This name pair has sufficient orthographic and phonetic differences.
19.	Fortaz	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Fotivda **Established name:** tivozanib **Dosage form:** capsules **Strength(s):** 1 mg and 1.5 mg **Usual Dose:** 1.5 mg once daily for 21 days	**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**
20.	Fortesta	65	This name pair has sufficient orthographic differences. Orthographically, the infix (est versus ivd) look sufficiently different and gives the names different shapes when scripted. Phonetically, the ending sounds in the 2nd syllables (v in tiv vs. s in tes) provide slight phonetic difference. Although Fotivda and Fortesta share numerical similarity in the dose (1 capsule vs. 1 pump) and strength (1 mg vs. 10 mg), the name pair do not overlap in other product characteristics: route of administration (oral vs. topical) and dosage form (capsules vs. gel). Additionally, Fortesta is a controlled substance (CIII) and must include the product strength, directions for use and quantity to dispense on a prescription.[h] Taking the above information into consideration, the likelihood of a verbal order where the difference in product characteristics (dose: capsule vs. pump; strength: 1 vs. 10; route of administration, and dosage form) will be overhead or missed is very low, thus the risk of name confusion between the name pair is minimized.
21.	Fortical	57	This name pair has sufficient orthographic and phonetic differences.

[h] Code of Federal Regulations. 21 CFR Part 1306.05(a)

No.	**Proposed name:** Fotivda **Established name:** tivozanib **Dosage form:** capsules **Strength(s):** 1 mg and 1.5 mg **Usual Dose:** 1.5 mg once daily for 21 days	**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**
22.	(b) (4)***	64	This name pair has sufficient orthographic and phonetic differences. Although both Fotivda and (b) (4)*** are capsules and have similar doses (1 capsule vs (b) (4) capsules), Fotivda will be supplied in multiple non-overlapping strengths (1 mg and 1.5 mg vs. (b) (4) mg) where a strength is needed for dispensing. Additionally, the Fotivda and (b) (4)*** do not overlap in milligram dose (1 mg or 1.5 mg vs. (b) (4) mg).
23.	(b) (4)***	67	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
24.	Activase	43
25.	Activella	47
26.	Aptivus	48
27.	Cabometyx	24
28.	Factive	54
29.	Forteo	44
30.	Inlyta	30
31.	Latuda	48
32.	Orbactiv	42
33.	Rectiv	39
34.	Sorafenib	36
35.	Sutent	41
36.	Ultiva	53
37.	Vibativ	49
38.	Votrient	48
39.	Zorbtive	42

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
40.	Asta Vita	56	Name identified in (b) (4) external study. Unable to find product characteristics in commonly used drug databases.
41.	(b) (4) ***	60	This is an alternate proposed proprietary name for IND (b) (4) was approved under proprietary name (b) (4)
42.	Fortacin	56	Name identified in external study. International product marketed in Italy, Spain, United Kingdom, and Ireland.
43.	(b) (4) ***	57	Proposed proprietary name withdrawn by the Applicant. ANDA 209323 was approved on 3/6/2020 without a proprietary name. Additionally, (b) (4)
44.	(b) (4) ***	58	Name was found unacceptable by CBER's Advertising and Promotional Labeling Branch on (b) (4)
45.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) withdrawn by Applicant on January 18, 2018. BLA 761097 approved under the proprietary name, Libtayo.

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

No.	Name	POCA Score (%)
46.	Boniva	58
47.	Dofetilde	56
48.	(b) (4) ***	56
49.	Koate Dvi	56
50.	Novafed A	55
51.	Onivyde	57

[i] 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

No.	Name	POCA Score (%)
52.	(b) (4) ***	56
53.	Potaba	56
54.	(b) (4) ***	59
55.	Solvadi	55
56.	Sorbid Sa	55
57.	Sovaldi	60
58.	Sufenta	56
59.	Tanabid Da	56
60.	Tavist Da	60
61.	Vidaza	55
62.	Zotex-D	55

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/s/

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