

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125516Orig1s000

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 30, 2014
Application Type and Number:	BLA 125516
Product Name and Strength:	Unituxin (Dinutuximab) Injection, 17.5 mg/5 mL (3.5 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	United Therapeutics, Corp.
Submission Date:	April 15, 2014
Panorama #:	2014-17228
DMEPA Primary Reviewer:	Otto L. Townsend, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Unituxin, from a safety and promotional 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 April 15, 2014 proprietary name submission.

- Intended Pronunciation: yoo-ni-TUX-in
- Active Ingredient: Dinutuximab
- Indication of Use: Treatment of high risk neuroblastoma
- Route of Administration: Intravenous Infusion
- Dosage Form: Injection
- Strength: 17.5 mg/5 mL (3.5 mg/mL)
- Dose and Frequency: 17.5 mg/m²/day intravenously over 10 to 20 hours daily for 4 days.
- How Supplied: Single-use vials
- Storage: Refrigerated

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's promotional 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 name¹.

¹USAN stem search conducted on May 8, 2014.

2.2.2 Components of the Proposed Proprietary Name

United Therapeutics, Corp. indicated in their submission that the proposed name, Unituxin, is not derived from any particular concept. This proprietary name is comprised of a single word that does not contain any components, such as a modifier, route of administration, or dosage form.

2.2.3 FDA Name Simulation Studies

110 practitioners participated in DMEPA's prescription studies. One interpretation from the verbal prescription study overlapped with a formerly marketed product, Uni-Tussin. Our search of the FDA's Phonetic and Orthographic Computer Analysis (POCA) system also retrieved the name, Unitussin. The source of the name was the RxNorm database. We were unable to find complete product characteristics for this formerly marketed over-the-counter product in commonly used drug databases (Drug@FDA, Redbook, DailyMed and Facts&Comparisons). Also, Google and Amazon searches did not find Uni-Tussin or Unitussin available for sale. However, we did determine that the Uni-Tussin product line was formerly marketed with guaifenesin as the active ingredient with or without a cough suppressant by United Research Laboratories (now URL Pharma, a subsidiary of Sun Pharma USA). A search of the website for Sun Pharma USA did not retrieve the Uni-Tussin brand or the active ingredient, guaifenesin as current product offerings. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 5, 2014 e-mail, the DOP2 did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	4
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	247
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 251 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DOP2 via e-mail on May 30, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP2 on June 9, 2014, they stated no additional concerns with the proposed proprietary name, Unituxin.

3 CONCLUSIONS

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

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 15, 2014 submission are altered, 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 considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment:** For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE 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.²

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

² National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

- 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 50% 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (See Table 3)
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

- 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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to 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 do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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 $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<p>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 have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ 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
<p>Step 2</p>	<p>Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names with overlapping or similar strengths or doses.</p>

<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product in a prescription simulation study). In such instances, FDA 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. Unituxin Study (Conducted on May 1, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p data-bbox="191 491 428 525"><u>Medication Order:</u></p> <p data-bbox="191 541 922 613">Unituxin 43.75 mg intravenous infusion</p> <p data-bbox="191 638 496 672"><u>Outpatient Prescription:</u></p> <div data-bbox="196 695 927 1150" style="border: 1px solid black; padding: 5px;"><p data-bbox="224 722 878 751">Patient _____ Date <u>5-1-14</u></p><p data-bbox="224 758 878 787">Address _____</p><p data-bbox="240 793 289 848">R</p><p data-bbox="207 890 350 1010"></p><p data-bbox="423 831 862 982"><i>Unituxin</i> <i>Bring to Infusion center</i> <i>#8</i></p><p data-bbox="224 1024 889 1054">Refill(s): _____ Dr. <u>OSE</u></p><p data-bbox="224 1060 889 1089">DEA No. _____ Address _____</p><p data-bbox="467 1096 889 1125">Telephone _____</p></div>	<p data-bbox="954 491 1317 600">“Unituxin. Directions are to bring to Infusion Center. Dispense 8”</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

**273 People Received Study
110 People Responded**

Study Name: Unituxin

	Total	36	38	36	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
??TUXIN	0	0	1	1	
AMTUXIN	1	0	0	1	
ANITUPIN	0	0	3	3	
ANITUXIN	0	0	1	1	
AVITUPIN	0	0	1	1	
CENATUXIN	0	0	1	1	
CENTUPIN	0	0	2	2	
CERETUXIN	0	0	1	1	
CEVITUXIN	0	0	1	1	
CINITUPIN	0	0	2	2	
CINITUXIN	0	0	1	1	
CUVETUPIN	0	0	1	1	
LEMTUXIN	1	0	0	1	
LENETUPIN	0	0	1	1	
LENITUXIN	1	0	0	1	
LEVETUPIN	0	0	1	1	
LEVITUPIA	0	0	1	1	
LIMITUXIN	3	0	0	3	
LIMTRIXIN	1	0	0	1	
LIMTUPIN	0	0	1	1	
LIMTUXIN	2	0	0	2	
LINETUPIN	0	0	1	1	
LINETUXIN	0	0	1	1	
LINITUPIN	0	0	2	2	
LINITURPIN	1	0	0	1	
LINITUXIN	9	0	1	10	

LINTURXIN?	1	0	0	1
LIVATUPIN	0	0	1	1
LIVITUPIN	0	0	1	1
LIVITUXIN	3	0	0	3
LIVTUXIN	1	0	0	1
LUITEXIN	1	0	0	1
LUMTURXIN	1	0	0	1
LUMTUXIN	1	0	0	1
SIMTERXIN	1	0	0	1
SOUNDS LIKE A CHEM MED	0	0	1	1
UMITURPIN	1	0	0	1
UNATAXIN	0	1	0	1
UNATUXIB	0	1	0	1
UNATUXIN	0	3	0	3
UNITAXIN	0	2	0	2
UNITEXIN	0	8	0	8
UNITOXIN	0	4	0	4
UNITRIXIN	0	0	1	1
UNITUPIN	0	0	3	3
UNITUSSIN	0	1	0	1
UNITUXAN	0	2	0	2
UNITUXEN	0	1	0	1
UNITUXIN	6	12	2	20
UNITUXON	0	2	0	2
UNITUXSON	0	1	0	1
UNTUPIN	0	0	1	1
UVITUXIN	0	0	1	1
ZELENTIN	0	0	1	1
ZINITURXIN	1	0	0	1

Appendix C: Highly Similar Names (i.e., combined POCA score is $\geq 70\%$)

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 days.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Unituxin	100	Name is subject of this review.
2.	Uni-Tussin	82	Name identified in RxNorm database. Unable to find complete product characteristics for this formerly marketed OTC product in commonly used drug databases (Drug@FDA, Redbook, DailyMed and Facts&Comparisons). Also, Google and Amazon search did not find Uni-Tussin for sale. The Uni-Tussin product line was formerly marketed as guaifenesin with or without a cough suppressant by United Research Laboratories (now URL Pharma, a subsidiary of Sun Pharma USA). A search of the website for Sun Pharma USA did not retrieve the Uni-Tussin or the active ingredient guaifenesin as current product offerings.
3.	UNITENSEN	74	Brand Unitensen has been withdrawn with no generic available per Drugs@FDA. NDA 008814 withdrawn FR effective date: 3/2/1994. NDA 009217 withdrawn FR effective date: 04/01/1994.
4.	Nioxin	70	The prefix and infix of this name pair have sufficient orthographic differences. Nioxin is an over-the-counter product line that is available as a topical shampoo for the treatment of dandruff and seborrheic dermatitis and as a topical scalp treatment for thinning hair.

Appendix D: Moderately Similar Names (i.e., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Proposed Name	POCA Score (%)
1.	MEFOXIN	62
2.	Uni-Guaifen 600/300	62
3.	Uramaxin	60
4.	CYTOXAN	58
5.	difenoxin	58
6.	Prudoxin	58

No.	Proposed Name	POCA Score (%)
7.	Sumaxin	58
8.	Trepoxen-250	58
9.	BIAXIN	57
10.	Natamycin	57
11.	Myoxin	56
12.	NATACYN	56
13.	Onexton***	56
14.	SudaTex-G	56
15.	Tinactin	56
16.	TriOxin	56
17.	UNIPEN	56
18.	NYSTATIN	55
19.	XIFAXAN	55
20.	Momexin	54
21.	Nicosyn	54
22.	Nitric Acid	54
23.	SURFAXIN	54
24.	Viroxyn	54
25.	MINITRAN	53
26.	Sudatex DM	53
27.	DELAXIN	52
28.	NUTROPIN	52
29.	QUIXIN	52
30.	Zeroxin	52
31.	ANESTACON	51
32.	MYCITRACIN	51
33.	Reumacetin	51
34.	BENOQUIN	50
35.	CILOXAN	50
36.	Desitin	50
37.	G-Myticin	50
38.	Ketotifen	50
39.	NAFTIN	50
40.	Podactin	50
41.	U-Lactin	50
42.	Unburn	50

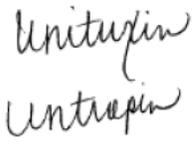
Appendix E: Moderately Similar Names (i.e., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
1.	Amikacin	51	<p>The name pair appears similar in shape and size; however, when scripted they appear dissimilar.</p>  <p>The first, second, and third syllables of this name pair sound different.</p>
2.	Antitussin	66	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The first two syllables of this name pair sound different.</p>
3.	Antitussin DM	52	<p>If the modifier is excluded, the infixes of this name pair have sufficient orthographic differences.</p> <p>If the modifier is excluded, the first and second syllables of this name pair sound different.</p>
4.	Avonex Pen	50	<p>If the modifier is excluded, the infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>If the modifier is excluded, Unituxin contains an extra syllable and all syllables in A-vo-nex sound different from yoo-ni-TUX-in.</p>
5.	Baltussin	52	<p>The prefixes of this name pair have sufficient orthographic differences.</p> <p>Unituxin contains an extra syllable and the beginning syllables of the name pair (Bal vs. yoo-ni-) sound different.</p>

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
6.	BETAXON	58	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (Be vs. yoo-ni-) sound different.
7.	Biotussin	56	The prefixes of this name pair have sufficient orthographic differences. The first and second syllable of this name pair sound different.
8.	cetuximab	52	The suffixes of this name pair have sufficient orthographic differences. When compared to each other, all syllables of this name pair sound different.
9.	CINOXACIN	51	The infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
10.	DESOXYN	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (De-so vs. yoo-ni-TUX) sound different.
11.	DIGOXIN	67	The prefixes and infix of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (Di-ja vs. yoo-ni-) sound different.
12.	Dioctyn	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable, and all syllables of the name pair sound different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
13.	Ditussin-HC	54	If the modifier is excluded, the prefixes of this name pair have sufficient orthographic differences. If the modifier is excluded, Unituxin contains an extra syllable and the beginning syllables of the name pair (Di vs. yoo-ni-) sound different.
14.	Donatuss XP	50	If the modifier is excluded, the prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (Do-na vs. yoo-ni-) sound different.
15.	Donatussin	66	The prefixes of this name pair have sufficient orthographic differences. The first two syllables of this name pair sound different.
16.	Donatussin DC	51	If the modifier is excluded, the prefixes of this name pair have sufficient orthographic differences. If the modifier is excluded, the first two syllables of this name pair sound different.
17.	Donatussin DM	51	If the modifier is excluded, the prefixes of this name pair have sufficient orthographic differences. If the modifier is excluded, the first two syllables of this name pair sound different.
18.	EC NAPROXEN	53	If the modifier is excluded, the prefixes and infixes of this name pair have sufficient orthographic differences. If the modifier is excluded, Unituxin contains an extra syllable and the beginning syllables of the name pair (Na-pro vs. yoo-ni-) sound different.
19.	Endur-Acin	51	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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.	ERBITUX	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and all syllables of the name pair sound different.
21.	EULEXIN	54	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the second syllable of the name pair (le vs. ni) sounds different.
22.	Funduscein	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and all syllables of the name pair sound different.
23.	FUNDUSCEIN-25	56	If the modifier is excluded, the prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. If the modifier is excluded, Unituxin contains an extra syllable and all syllables of the name pair sound different.
24.	Gani-Tuss NR	54	If the modifier is excluded, the prefixes of this name pair have sufficient orthographic differences. If the modifier is excluded, Unituxin contains an extra syllable and the first syllable of the name pair (Ga vs. yoo) sounds different.
25.	Guaiatussin	52	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
26.	INDOCIN	52	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (In-do vs. yoo-ni-) sound different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
27.	INSULIN	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and all syllables of the name pair sound different.
28.	INTROPIN	50	When scripted, Unituxin and Intropin appear similar in appearance; however, the letter, “i” in the third position of Unituxin lengthens the prefix. Thus, differentiating the name pair.  Unituxin contains an extra syllable and the first and second syllables of the name pair (in vs. yoo, tru vs. nye) sound different.
29.	LANOXIN	61	The infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of the name pair (La vs. yoo-) sounds different.
30.	LONITEN	50	The infixes and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first and third syllables of the name pair (Lo vs. yoo, ten vs. TUX) sound different.
31.	menotropin	50	The prefixes of this name pair have sufficient orthographic differences. When compared to each other, all syllables of this name pair sound different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
32.	Miniprin	54	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first and third syllables of the name pair (Mi vs. yoo, prin vs. TUX) sound different.
33.	MINOCIN	52	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of the name pair (Mi vs. yoo) sounds different.
34.	MINOXIDIL	50	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. When compared to each other, all syllables of this name pair sound different.
35.	MITOMYCIN	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
36.	MUTAMYCIN	50	The prefixes and infixes of this name pair have sufficient orthographic differences. When compared to each other, all syllables of this name pair sound different.
37.	Mytussin	58	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of the name pair (My vs. yoo) sounds different.
38.	NALOXONE	50	The suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
39.	Naltrexone	50	The infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable. When compared to each other, all syllables of this name pair sound different.
40.	NAPROXEN	62	The prefix and infix of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (Na-pro vs. yoo-ni-) sound different.
41.	Nexiclon	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (Ne-xi-clon vs. yoo-ni-TUX) sound different.
42.	Niacin	51	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin has two extra syllables and the first syllable of the name pair (Nia vs. yoo) sounds different.
43.	NOROXIN	62	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the beginning syllables of the name pair (No-ro vs. yoo-ni) sound different.
44.	Notuss-NXD	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Notus-NXD has an extra syllable and all syllables of the name pair sound different.
45.	ONCOVIN	50	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin has an extra syllable and all syllables of the name pair sound different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
46.	OXYTOCIN	50	The prefixes of this name pair have sufficient orthographic differences. Unituxin has an extra syllable and the first and second syllables of this name pair sound different.
47.	PENTOXIL	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and all syllables of the name pair sound different.
48.	Pertussin	50	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.
49.	PITOCIN	56	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.
50.	Poly-Tussin	50	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
51.	PRIMAXIN	54	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first and second syllables of this name pair sound different.
52.	Q-Tussin	50	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.
53.	Qual Tussin	52	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
54.	Ri-Tussin	56	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.
55.	RITUXAN	66	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.
56.	rituximab	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. When compared to each other, all syllables of this name pair sound different.
57.	Robitussin	62	The prefixes of this name pair have sufficient orthographic differences. The first two syllables of this name pair sound different.
58.	romidepsin	53	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
59.	Safe Tussin 30	52	If the modifier is excluded, the prefixes of this name pair have sufficient orthographic differences. If the modifier is excluded, Unituxin has an extra syllable. Also, the beginning syllables of this name pair (Safe vs. yoo-ni) sound different.
60.	Senexon	52	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.
61.	Siltussin	53	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of this name pair sounds different.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
62.	STAXYN	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin has two extra syllables and the first syllable of this name pair sounds different.
63.	Sudatex	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Unituxin has an extra syllable and the first two syllables of the name pair sound different.
64.	sunitinib	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. When compared to each other, all syllables of this name pair sound different.
65.	U-GENCIN	54	The prefixes and infixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the second syllable of the name pair (gen vs. ni) sounds different.
66.	UNASYN	51	The infixes and suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable “TUX”, which is not heard in U-na-syn.
67.	Uni-Cenna	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound differently.
68.	Uni-Tann	60	Uni-Tann (brand) is no longer available but generic alternative listed in RedBook is Dytan (Hawthorn Pharmaceuticals. Hawthorn website search (hawthornrx.com) links to Pernix Therapeutics (pernixtx.com) after click, but Pernix does not list Dytan as a product. Checked Amazon, DrugStore, & McKesson but didn’t find Uni-Tann or Dytan.

No.	Proposed name: Unituxin Strength(s): 17.5 mg/5mL (3.5 mg/mL) Usual Dose: 17.5 mg/m ² /day intravenously over 10 to 20 hours once daily for 4 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
69.	Uni-Tamm D	54	Uni-Tamm D (brand) is no longer available but generic alternative listed in RedBook is Dytan-D (Hawthorn Pharmaceuticals. Hawthorn website search (hawthornrx.com) links to Pernix Therapeutics (pernixtx.com) after click, but Pernix does not list Dytan-D as a product. Checked Amazon, DrugStore, & McKesson but didn't find Uni-Tamm D or Dytan-D.
70.	UNITHROID	54	The suffixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the ending syllables of the name pair (throid vs. TUX-in) sound different.
71.	Uni-Tricof HC	50	If the modifier is excluded, the suffixes of this name pair have sufficient orthographic differences. If the modifier is excluded, Unituxin contains an extra syllable and the ending syllables of the name pair (tricof vs. TUX-in) sound different.
72.	Vitussin	62	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable and the first syllable of the name pair sounds different.
73.	Yodoxin	54	The prefixes of this name pair have sufficient orthographic differences. Unituxin contains an extra syllable "ni", which is not heard in Yo-do-xin.

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

No.	Name	POCA Score (%)
1.	Not applicable	

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.	NEUTREXIN	69	Product no longer marketed. Withdrawn due to decreased demand. FR effective date: 3/13/2009
2.	Uni Tussin CF	68	Name identified in RxNorm database. Unable to find complete product characteristics for this formerly marketed OTC product in commonly used drug databases (Drug@FDA, Redbook, Facts & Comparison). Also, Google and Amazon search did not find Uni Tussin CF for sale.
3.	Uni Tussin PE	68	Name identified in RxNorm database. Unable to find complete product characteristics for this formerly marketed OTC product in commonly used drug databases (Drug@FDA, Redbook, Facts & Comparison). Also, Google and Amazon search did not find Uni Tussin PE for sale.
4.	Uni-Tex	68	Product no longer marketed. No generic alternatives currently marketed.
5.	Uni-Tussin DM	68	Name identified in RxNorm database. Unable to find complete product characteristics for this formerly marketed OTC product in commonly used drug databases (Drug@FDA, Redbook, Facts&Comparison). Also, performed Google search and checked amazon.com for currently marketed products.
6.	Unit-Tex	66	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
7.	Digitoxin	65	Product no longer marketed in injectable form. Available as bulk powder for compounding. FR effective date: 1/14/1993
8.	flunixin	64	Veterinary Product
9.	Uni Tuss DM	64	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
10.	Uni-Tren	64	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
11.	Uniparin	63	International product formerly marketed in Australia and the United Kingdom.
12.	Dynaxin	62	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
13.	Mitoxana	62	International product marketed in the United Kingdom.
14.	Napeoxen	62	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
15.	Uni Decon	62	Product withdrawn from the market due to safety concerns. Product contained phenylpropanolamine.
16.	(b) (4)***	62	Name was entered by SE .Unable to find product characteristics in commonly used drug databases. Similar spelling to Xifaxan (see Appendix D).
17.	Ciproxin	61	International product marketed in several foreign countries.
18.	Medigoxin	61	International product formerly marketed in Poland.
19.	Antepsin	60	International product marketed in several foreign countries.
20.	Endoxan	60	International product marketed in several foreign countries.
21.	Naturetin	60	Brand discontinued with no generic available. NDA 012164 withdrawn FR Effective: 3/13/2009
22.	NATURETIN-10	60	Brand discontinued with no generic available. NDA 012164 withdrawn FR Effective: 3/13/2009
23.	NATURETIN-2.5	60	Brand discontinued with no generic available. NDA 012164 withdrawn FR Effective: 3/13/2009
24.	NATURETIN-5	60	Brand discontinued with no generic available. NDA 012164 withdrawn FR Effective: 3/13/2009

No.	Name	POCA Score (%)	Failure preventions
25.	Uni Tan CS	60	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases. Name may be a variant of Uni-Tann CS (see #28 below).
26.	Detussin	59	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
27.	Un-Aspirin	59	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
28.	Uni-Tann CS	59	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
29.	Clonixin	58	International established name of an NSAID marketed under various proprietary names in several foreign countries.
30.	(b) (4)***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). An alternative name has not been submitted.
31.	(b) (4)***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). DMEPA has conditionally approved the name, (b) (4)*** (OSE # (b) (4) (b) (4)).
32.	RAUDIXIN	58	Brand discontinued with no generic available. NDA 008842 withdrawn FR Effective: 9/29/1995.
33.	SULSOXIN	58	Brand discontinued with no generic available. NDA 080040 withdrawn FR Effective: 12/22/1993
34.	amineptin	57	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
35.	bunazosin	57	International established name of an alpha 1-adrenoceptor blocker marketed in Japan.
36.	CHIBROXIN	57	Brand discontinued with no generic available. NDA 019757 withdrawn FR Effective: 6/4/2004

No.	Name	POCA Score (%)	Failure preventions
37.	Naproxrn	57	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
38.	Uni Tuss HC	57	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
39.	Amtussin	56	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
40.	Centussin	56	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
41.	Enoxacin	56	Brand discontinued with no generic available. NDA 019616 withdrawn FR Effective: 4/4/2005
42.	Duraxin	55	International product marketed in Puerto Rico.
43.	(b) (4)***	55	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). Product approved as Mitosol (NDA 022572).
44.	Molipaxin	55	International product marketed in several foreign countries.
45.	Natulan	55	International product marketed in several foreign countries.
46.	Pneumotussin	55	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
47.	Pneumotussin 2.5	55	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
48.	Albatussin	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
49.	Ampitrin	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
50.	BENDECTIN	54	Brand discontinued with no generic available. NDA 010598 withdrawn FR Effective: 3/13/2009
51.	butibufen	54	International established name of an NSAID formerly marketed in Spain.
52.	(b) (4)***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). Product approved under new proprietary name, Intuniv.
53.	Dibekacin	54	International established name of aminoglycoside antibiotic marketed under various proprietary names in several foreign countries.
54.	Endoxana	54	International product marketed in the United Kingdom.
55.	etifoxine	54	International established name of an anxiolytic marketed under various proprietary names in several foreign countries.
56.	Immunoprin	54	International product marketed in several foreign countries.
57.	Mastussin	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
58.	(b) (4)***	54	This is a secondary proposed proprietary name. The product was approved under proprietary name, (b) (4)*** (OSE # (b) (4), (b) (4)).
59.	NETROMYCIN	54	Brand discontinued with no generic available. NDA 050544 withdrawn FR Effective: 9/17/2003
60.	Nitrocine	54	International product marketed in several foreign countries.
61.	Nitrogen	54	Product is not a drug. It is a chemical element contained in drug compounds.
62.	Nitrotan	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
63.	Pimafucin	54	International product marketed in several foreign countries.

No.	Name	POCA Score (%)	Failure preventions
64.	Uni-Antacid	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
65.	Uniferon	54	International product marketed in the Philippines.
66.	Unipine XL	54	International product formerly marketed in the United Kingdom.
67.	Uniprim	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
68.	Uni-Tris	54	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
69.	A-G Tussin	53	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
70.	Cardoxin	53	International product marketed in Israel.
71.	(b) (4) ***	53	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). An alternative name has not been submitted. (IND (b) (4))
72.	Micturin	53	International product marketed in the United Kingdom.
73.	Obidoxime	53	International established name of a cholinesterase reactivator marketed in several foreign countries.
74.	panixine	53	Brand discontinued with no generic available. ANDA 065100 withdrawn FR Effective: 9/21/2012.
75.	4-anisic acid	52	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
76.	(b) (4) ***	52	This is a secondary proposed proprietary name and the product was approved under proprietary name, Dificid (NDA 201699).
77.	Enditussin-HD	52	Product withdrawn from the market due to safety concerns. Product contained phenylpropanolamine.
78.	Evoxin	52	International product formerly marketed in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
79.	Flunisin	52	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
80.	Green-Tussin	52	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
81.	Idoxene	52	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
82.	Incurin	52	International veterinary product marketed in several foreign countries.
83.	indobufen	52	International established name of a reverse cyclooxygenase inhibitor marketed in several foreign countries.
84.	Junifen	52	International product formerly marketed in several foreign countries.
85.	Monensin	52	Veterinary Product
86.	Muripsin	52	International product marketed in the United Kingdom.
87.	Netilmicin	52	Established name of an aminoglycoside antibiotic marketed under various proprietary names in several foreign countries. Formerly marketed in the United States (see Netromycin row # 59 above).
88.	Nitoman	52	International product marketed in several foreign countries.
89.	nitroxoline	52	Internationalestablished name of an antibacterial/antifungal agent marketed under various proprietary names in several foreign countries.
90.	Razoxin	52	International product marketed in the United Kingdom.
91.	Rimoxyn	52	International product formerly marketed in the United Kingdom.
92.	Suda-Tussin DM	52	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.

No.	Name	POCA Score (%)	Failure preventions
93.	Unilax	52	Product withdrawn from the market due to safety concerns because it contained phenolphthalein.) FR Effective: 1/29/1999. Currently marketed in Singapore with bisacodyl as active ingredient.
94.	Uni-Mint	52	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
95.	Zeniquin	52	Veterinary Product
96.	cethixim	51	International product marketed in Indonesia.
97.	Co-Tussin	51	International product marketed in Thailand.
98.	Entaprin	51	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
99.	methixene	51	Brand discontinued with no generic available. NDA 065100 withdrawn FR Effective: 9/21/2012.
100.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). Entire application withdrawn by the Applicant.
101.	(b) (4) ****	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). Product approved under new proprietary name Qudexy XR (NDA 205122).
102.	Uritin	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
103.	AFAXIN	50	Brand discontinued with no generic available. ANDA 083187 withdrawn FR Effective 11/19/1997
104.	Aminopterin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
105.	Anatuss DM	50	Brand discontinued with no generic available. ANDA 083187 withdrawn FR Effective: 11/19/1997
106.	Bimectin	50	Veterinary Product

No.	Name	POCA Score (%)	Failure preventions
107.	C Tussin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
108.	Draxxin	50	Veterinary Product
109.	Endo-Mectin	50	Veterinary Product
110.	Flucloxin	50	International product marketed in New Zealand.
111.	Genestin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
112.	Genticin	50	International product marketed in the United Kingdom.
113.	GRISACTIN	50	Brand discontinued with no generic available. NDA 050051 and withdrawn FR Effective: 06/04/2004.
114.	Grisactin 250	50	Brand discontinued with no generic available. NDA 050051 and withdrawn FR Effective: 06/04/2004.
115.	Grisactin 500	50	Brand discontinued with no generic available. ANDA 060212 and withdrawn FR Effective: 06/05/2006.
116.	Hydroxin	50	International brand formerly marketed in Thailand.
117.	Immukin	50	International product marketed in several foreign countries.
118.	MESANTOIN	50	Brand discontinued with no generic available. NDA 006008 and withdrawn FR Effective: 08/20/2010. Per Federal Register notice, dated 1/30/2009, FDA announced its determination that product was not withdrawn from sale due to safety or effectiveness.
119.	Metatensin	50	Brand discontinued with no generic available. NDA 012972 and withdrawn FR Effective: 06/04/2004
120.	METATENSIN #2	50	Brand discontinued with no generic available. NDA 012972 and withdrawn FR Effective: 06/04/2005
121.	METATENSIN #4	50	Brand discontinued with no generic available. NDA 012972 and withdrawn FR Effective: 06/04/2006

No.	Name	POCA Score (%)	Failure preventions
122.	MITHRACIN	50	Brand discontinued with no generic available. NDA 050109 and withdrawn FR Effective: 06/18/2009
123.	nitarsone	50	Veterinary Product
124.	Noxene	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
125.	Ocutricin	50	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.
126.	Ornipressin	50	International established name of a synthetic derivative of vasopressin marketed in several foreign countries.
127.	Paloxin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
128.	Phenacetin	50	All products containing Phenacetin withdrawn from the market or reformulated due to safety concerns. FR effective: 11/4/1983.
129.	Pyrithioxin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
130.	Tab Tussin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
131.	Tenkicin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
132.	(b) (4) ***	50	This is a secondary proposed proprietary name. An acceptable proprietary name has not been approved. (IND (b) (4)).

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/s/

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06/30/2014

CHI-MING TU
06/30/2014