CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217338Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	September 12, 2025
Application Type and Number:	NDA 217338
Product Name, Dosage Form, and Strength:	Mucinex 12 HR Cold & Fever Multi-Symptom (naproxen sodium/dextromethorphan HBr/guaifenesin) extended-release tablets, 110 mg/30 mg/600 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Over-the-counter (OTC)
Applicant/Sponsor Name:	RB Health US LLC (RB)
PNR ID #:	2025-1044726587
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, 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. RB did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

RB previously submitted the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, under NDA 217338 on December 19, 2023. We found the name conditionally acceptable on March 8, 2024.[a]

NDA 217338 received a Complete Response (CR) letter on July 26, 2024. RB submitted a Class 2 Resubmission for NDA 217338 in response to the CR letter on July 7, 2025, and submitted the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, for review on July 11, 2025. We note that all product characteristics in this current submission remain the same since our last March 8, 2024 review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 11, 2025[b].

Table 1. Relevant Product Information for Mucinex 12 HR Cold & Fever Multi-Symptom	
Intended pronunciation:	Myoo·suh·neks twelv aʊr koʊld ænd ˈfiː.və· mʌl.ti-ˈsɪmp.təm
Active ingredient:	naproxen sodium/dextromethorphan HBr/guaifenesin

Indication:	Drug Facts label (DFL) *Uses*:
	• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
	• temporarily relieves:
	  • cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
	  • the intensity of coughing
	  • the impulse to cough to help you get to sleep
	  • minor aches and pains due to headache and the common cold
	• temporarily reduces fever

[a] Jones, G. Proprietary Name Review for Mucinex 12 HR Cold & Fever Multi-Symptom (NDA 217338). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 MAR 08. PNR ID No. 2023-1044725519.

[b] Proprietary Name/Request for Review for NDA 217338 Mucinex 12 HR Cold & Fever Multi-Symptom. Parsippany (NJ): RB Health US LLC; 2025 JUL 11. Available from: \\CDSESUB1\EVSPROD\nda217338\0024\m1\us\118-prop-names\prop-names.pdf.

Table 1. Relevant Product Information for Mucinex 12 HR Cold & Fever Multi-Symptom	
Dosage Form:	extended-release tablets
Strength:	110 mg/30 mg/600 mg
Route of administration:	oral
Dose and frequency:	DFL *Directions*: • do not crush, chew, or break extended-release tablet • do not take more than directed • take each dose with a full glass of water. • adults and children 12 years and older: take 2 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours • children under 12 years of age: do not use
How Supplied:	4-count blister card (b) (4) 8-count blister card (b) (4) 10-count blister card (b) (4) 4-count carton containing one 4-count blister card 8-count carton containing one 8-count blister card 16-count carton containing two 8-count blister cards 32-count carton containing four 8-count blister cards 60-count carton containing six 10-count blister cards
Storage:	store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F)
Listed Drug:	○ Mucinex DM (guaifenesin and dextromethorphan HBr extended-release tablets) NDA 021620 ○ Aleve (naproxen sodium tablets) NDA 020204 ○ Aleve-D Sinus and Cold (naproxen sodium and pseudoephedrine HCl extended-release tablets) NDA 021076

2 DISCUSSION

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom.

2.1 MISBRANDING ASSESSMENT AND REVIEW DISCIPLINE INITIAL COMMENTS

At the initial phase of the review, the Division of Nonprescription Drugs I (DNPD I) did not have misbranding concerns with the proposed proprietary name. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the DNPD I's assessment and determined that the name Mucinex 12 HR Cold & Fever Multi-Symptom would not misbrand the proposed product.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom.

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

RB indicated in their submission that the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, is an extension of the Mucinex brand, which is well known for upper respiratory relief, and the proposed proprietary name helps consumers to differentiate it from other Mucinex extended-release tablets when selecting products.

This proprietary name is comprised of multiple words, the root name, Mucinex, and the modifiers, 12 HR Cold & Fever Multi-Symptom.

The root name, Mucinex, contains the letter strings "in" and "ex", which are medical abbreviations for "intranasal" and "extra strength", respectively. The modifier "Cold" contains the letter string "ld", and the modifier "Fever" contains the letter string "er", which are medical abbreviations for "low dose" and "extended release", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, in this instance, we have no expectation that the words "Mucinex", "Cold", and "Fever" would be spelled differently to avoid containing a medical abbreviation. Also, the modifier "Cold" and "Fever" describe the use of the proposed product. Thus, we do not object to the inclusion of the letter strings "in", "ex", "ld", and "er" in the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

See Section 2.1 Misbranding Assessment and Review Discipline Initial Comments.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-four (84) practitioners participated in FDA's prescription simulation studies for Mucinex 12 HR Cold & Fever Multi-Symptom.

One respondent in the Inpatient study omitted all the modifiers, "12 HR Cold & Fever Multi-Symptom", misinterpreting the proposed proprietary name as "Mucinex", which contains the active ingredient guaifenesin. We further evaluate the use of the root name "Mucinex" and the proposed modifiers in Section 2.2.5.

Two respondents in the Inpatient (n=1) and Voice (n=1) studies omitted the modifiers, "Cold & Fever Multi-Symptom", misinterpreting the proposed proprietary name as "Mucinex 12 HR", four respondents in the Inpatient (n=1) and Outpatient (n=3) studies omitted the modifier, "Multi-Symptom", misinterpreting the proposed proprietary name as "Mucinex 12 HR Cold &

[c] USAN stem search conducted on August 1, 2025.

Fever", and two respondents in the Computerized Prescription Order Entry (CPOE) study omitted the modifier "Multi-Symptom", incorrectly selecting "Mucinex 12 Cold, Flu and Cough". In this instance, no "Mucinex 12 HR", "Mucinex 12 HR Cold & Fever", or "Mucinex 12 Cold, Flu and Cough" products are marketed; thus, users would likely receive the Mucinex 12 HR Cold & Fever Multi-Symptom product, and the risk of name confusion is acceptable in this case.

The remaining 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.

2.2.5 SAFETY ANALYSIS OF THE ROOT NAME MUCINEX AND PROPOSED MODIFIERS, 12 HR COLD & FEVER MULTI-SYMPTOM

The proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, is comprised of the root name, Mucinex, and the modifiers, 12 HR Cold & Fever Multi-Symptom.

1. Evaluation of the use of the same root name, Mucinex

The root name, Mucinex, has been the proprietary name for guaifenesin extended-release tablets since its approval on July 12, 2002, for the nonprescription indication as an expectorant: to help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. RB stated in the submission that "Mucinex" in the Mucinex product line consists of a range of products containing guaifenesin, which relieves chest congestion. The proposed product contains the active ingredient guaifenesin, and the first bullet in the proposed DFL *Uses* is the same expectorant indication:

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Additionally, our routine post-marketing surveillance of nonprescription drug products has not identified name confusion medication error concerns associated with Mucinex that warrants regulatory action. Therefore, we find the use of the root name, Mucinex, acceptable.

2. Evaluation of the use of the modifiers to differentiate the product

The use of a modifier is a common naming practice to differentiate products within a nonprescription drug family product line. Modifiers can assist in differentiating products and may help to prevent potential selection errors when used; however, omission and oversight of modifiers is cited in literature as a common cause of medication errors.[d] Postmarket experience shows that family branding may result in medication errors if the modifier is omitted, and the product characteristics are similar or overlap. As observed in the FDA Name Simulation Study, one respondent omitted all the modifiers in the response, which alludes to the potential risk for selection error between the Mucinex product line. However, as there are currently three extended-release tablet products in the Mucinex product line (Mucinex, Mucinex D, and Mucinex DM), whereby such selection error risk already exists in the nonprescription marketplace. An alternative to using a modifier to distinguish this proposed product from the

[d] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

currently marketed products is to use a different root name. However, marketing a new product under a unique proprietary name also carries a risk of medication errors, such as therapeutic duplication and overdoses. Although the added modifier naming strategy is not devoid of risk because modifiers may be omitted; in this case, we find no objection to the use of modifiers to assist in differentiating between products.

3. Evaluation of the proposed modifiers, 12 HR Cold & Fever Multi-Symptom

RB stated in the submission that the proposed product is an extended-release formulation, dosed every 12 hours, whereby the use of "12 HR" in the proposed proprietary name reinforces the dosing interval and differentiates it from immediate-release formulations that are dosed every 4 hours. The acceptability of "12 HR" in the proposed proprietary name is dependent on the current review of the additional clinical study data submitted related to the proposed product's 12-hour dosing interval, which is still ongoing. Therefore, at the time of this review, acceptability of "12 HR" in the proposed proprietary name remains a review issue and is contingent on the review team's determination of the 12-hour dosing interval.

In addition to the active ingredient guaifenesin, which is contained in Mucinex, the proposed product contains the additional active ingredients, naproxen sodium and dextromethorphan hydrobromide. RB stated in the submission that "Cold & Fever" points to the combined active ingredients, i.e., dextromethorphan bromide and naproxen sodium, and their approved indications. The proposed DFL *Uses* include the indications for dextromethorphan bromide, which are:

- temporarily relieves: cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants, the intensity of coughing, the impulse to cough to help you get to sleep.

And the proposed DFL *Uses* include several of the indications for naproxen sodium as it relates to upper respiratory symptoms, pain, and fever:

- temporarily relieves minor aches and pains due to headache and the common cold and temporarily reduces fever.

Moreover, the use of "Cold" is already used in nonprescription nomenclature of currently marketed application products (e.g., Advil Cold and Sinus) to describe an indication of use, and we are not aware of name confusion concerns associated with the modifier "Cold" from our routine post-marketing surveillance of nonprescription drug products.

The use of "Fever" is novel in nonprescription nomenclature for application products. However, for the proposed product, the use of "Fever" accurately reflects the active ingredient naproxen and its proposed indication to relieve minor aches and pains and fever.

RB stated that "Multi-Symptom" points to the three active ingredients, which provides relief for multiple symptoms, including cough, minor aches and pain, and fever. Additionally, "Multi-Symptom" is already used in nonprescription nomenclature of currently marketed application products (e.g., Advil Multi-Symptom Cold & Flu and Imodium Multi-Symptom Relief) to describe a combination of multiple active ingredients and their respective indications of use. Also, we

are not aware of name confusion concerns associated with the modifier “Multi-Symptom” from our routine post-marketing surveillance of nonprescription drug products.

The proposed product contains three active ingredients, and we find that the proposed modifier “Cold & Fever Multi-Symptom” in the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, suggests the name of all the active ingredients in the proposed product (per 21 CFR 201.6(b)).

Therefore, based on the aforementioned reasons, we find the use of the proposed modifier “Cold & Fever Multi-Symptom” acceptable.

2.2.6 COMMUNICATION OF DMEPA2’S DETERMINATION

On September 12, 2025, DMEPA 2 communicated our determination to the Division of Nonprescription Drugs I (DNPDI).

3 CONCLUSION

The proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, is conditionally acceptable.

3.1 COMMENTS TO RB HEALTH US LLC

We have completed our review of the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, and have concluded that this proprietary name is conditionally acceptable.

If any of the proposed product characteristics as stated in your submission (e.g., the proposed 12-hour dosing interval), received on July 11, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review. Please note the proposed 12-hour dosing interval is still under review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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.[e]

Table 3. 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?

[e] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

Table 3. 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.	
	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. FDA Prescription Simulation Studies: DMEPA also conducts 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.

c. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and 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.

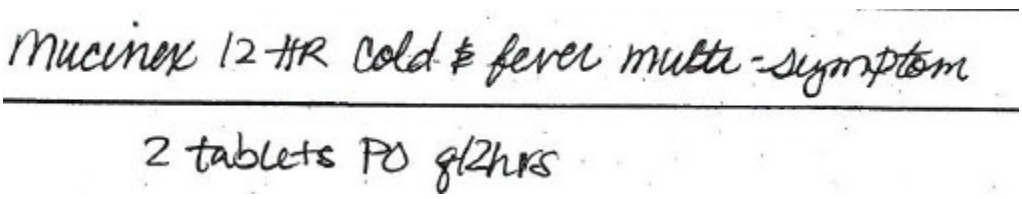
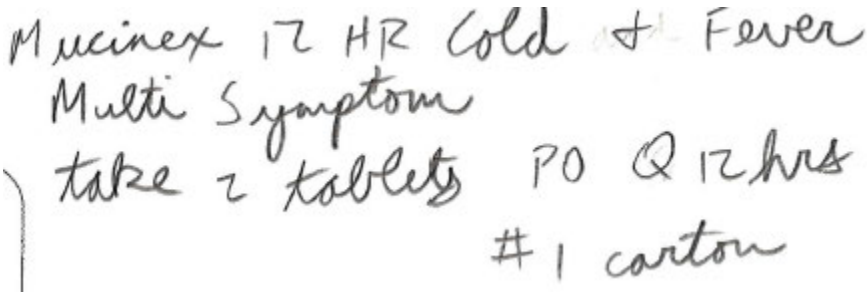
   Additionally, other review disciplines opinions such as OPQ may be considered depending on the proposed proprietary name.

   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 Safety Evaluator 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.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Mucinex 12 HR Cold & Fever Multi-Symptom Study (Conducted on 8/5/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Mucinex 12 HR Cold & Fever Multi-Symptom Take 2 tablets by mouth every 12 hours Dispense 1 carton
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Mucinex 12 HR Cold & Fever Multi-Symptom	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Mucinex 12 HR Cold & Fever Multi-Symptom People Received Study: 161 People Responded: 84					
Total	22	23	19	20	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MUCINEX	1	0	0	0	1
MUCINEX 12 HOUR COLD & FEVER MULTISYMPTOM	0	1	0	0	1
MUCINEX 12 COLD, FLU AND COUGH	0	0	0	2	2
MUCINEX 12 FR COLD & FEVER MULTI SYMPTOM	0	1	0	0	1
MUCINEX 12 HOUR COLD & FEVER MULTI-SYMPTOM	1	0	1	0	2
MUCINEX 12 HOUR COLD & FEVER MULTISYMPTOM	0	0	1	0	1

MUCINEX 12 HOUR COLD + FEVER MULTI SYMPTOM	0	1	0	0	1
MUCINEX 12 HOUR COLD AND FEVER MULIT-SYMPTOM	1	0	0	0	1
MUCINEX 12 HOUR COLD AND FEVER MULTI SYMPTOM	1	3	0	0	4
MUCINEX 12 HOUR COLD AND FEVER MULTI-SYMPTOM	1	0	4	0	5
MUCINEX 12 HOUR COLD AND FEVER MULTI-SYPTOM	0	1	0	0	1
MUCINEX 12 HOUR COLD AND FEVER MULTISYMPTOM	0	0	1	0	1
MUCINEX 12 HOURS COLD & FEVER MULTI SYMPTOM	1	0	0	0	1
MUCINEX 12 HOURS COLD AND FEVER MULTI SYMPTOMS	0	0	1	0	1
MUCINEX 12 HR	1	0	1	0	2
MUCINEX 12 HR COLD & FEVER	0	1	0	0	1
MUCINEX 12 HR COLD & FEVER MULTI SYMPTOM	0	2	0	0	2
MUCINEX 12 HR COLD & FEVER MULTI-SYMPTOM	7	0	0	17	24
MUCINEX 12 HR COLD & FEVER MULTISYMPTOMATIC	0	1	0	0	1
MUCINEX 12 HR COLD & FLU MULTI-SYMPTOM	0	0	0	1	1
MUCINEX 12 HR COLD + FEVER MULTI SYMPTOM	0	3	0	0	3
MUCINEX 12 HR COLD AND FEVER	0	1	0	0	1
MUCINEX 12 HR COLD AND FEVER MULTI SYMPTOM	0	6	1	0	7
MUCINEX 12 HR COLD AND FEVER MULTI-SYMPTOM	5	0	1	0	6
MUCINEX 12 HR COLD AND FEVERL MULTI SYMPTOM	0	1	0	0	1
MUCINEX 12-HOUR COLD AND FEVER MULTI-SYMPTOM	0	0	5	0	5
MUCINEX 12-HR COLD AND FEVER MULTISYMPTPOM	0	0	1	0	1
MUCINEX 12HR COLD & FEVER MULTI-SYMPTOM	2	0	0	0	2
MUCINEX 12HR COLD AND FEVER	1	1	0	0	2
MUCINEX 12HR COLD AND FEVER MULTISYMPTOM	0	0	1	0	1
MUSCINEX 12 HOUR COLD AND FEVER MULTISYSTEM	0	0	1	0	1

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

GRACE JONES
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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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Date of This Review:	March 8, 2024
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Product Type:	Multiple Ingredient Product
Rx or OTC:	Over-the-counter (OTC)
Applicant/Sponsor Name:	RB Health US LLC (RB)
PNR ID #:	2023-1044725519
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, 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. RB did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

RB previously submitted the proposed proprietary name, [redacted] (b) (4) *** under IND 105403 for naproxen sodium/dextromethorphan HBr/guaifenesin extended-release tablets on June 9, 2016, which DMEPA found acceptable on November 3, 2016.[a] RB submitted another proposed proprietary name, [redacted] (b) (4) *** on May 24, 2022 under IND 105403. RB later withdrew the proposed proprietary name, [redacted] (b) (4) *** on June 20, 2023, and withdrew the proposed proprietary name [redacted] (b) (4) *** under IND 105403 on October 16, 2023.

RB submitted the proposed proprietary name, [redacted] (b) (4) *** under NDA 217338 for naproxen sodium/dextromethorphan HBr/guaifenesin extended-release tablets on October 6, 2023. A teleconference with RB was held on December 6, 2023, to discuss preliminary findings for the proposed proprietary name.[b] Because at this time, it was identified that the listed drug products and the proposed product [redacted] (b) (4) Additionally, the review team also identified at this time the proposed product's 12-hour dosing interval is a review issue. On December 11, 2023, RB withdrew the proposed proprietary name, [redacted] (b) (4) ***.

RB submitted a new proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, for review on December 19, 2023 under NDA 217338. The proposed product's 12-hour dosing interval is still a review issue at the time of this name review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 19, 2023[c].

Table 1. Relevant Product Information for Mucinex 12 HR Cold & Fever Multi-Symptom

[a] Jones G. Proprietary Name Review for [redacted] (b) (4) *** (IND 105403). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 NOV 03. Panorama ID No. 2016-8042888.

[b] Olagundoye-Alawode A. General Advice Letter for NDA 217338. Silver Spring (MD): FDA, CDER, OSE (US); 2023 DEC 06. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8071ddf2

[c] Proprietary Name/Request for Review (NDA 217338 for Guaifenesin, Dextromethorphan Hbr, Naproxen Sodium). Parsippany (NJ): RB Health US LLC; 2023 DEC 19. Available from: \\CDSESUB1\EVSPROD\nda217338\0008\m1\us\118-prop-names\prop-names.pdf.

Table 1. Relevant Product Information for Mucinex 12 HR Cold & Fever Multi-Symptom	
Intended pronunciation:	Myoo·suh·neks twelv aʊr koʊld ænd ˈfiː.və mʌl.ti-ˈsɪmp.təm
Active ingredient:	naproxen sodium/dextromethorphan HBr/guaifenesin
Indication:	Drug Facts labeling (DFL) *Uses*: • helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive • temporarily relieves: o cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants o the intensity of coughing o the impulse to cough to help you get to sleep o minor aches and pains due to headache and the common cold • temporarily reduces fever
Dosage Form:	extended-release tablets
Strength:	110 mg/30 mg/600 mg
Route of administration:	oral
Usual dosage and frequency:	DFL *Directions*: • do not crush, chew, or break tablet • do not take more than directed • take each dose with a full glass of water • adults and children 12 years and older: take 2 tablets every 12 hours; not more than 4 tablets in (b) (4) 24 hours • children under 12 years of age: do not use
How Supplied:	4-count, 8-count, 10-count blister cards 4-count, 8-count, 16-count, 32-count, 60-count cartons
Storage:	store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).

2 DISCUSSION

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom.

2.1 MISBRANDING ASSESSMENT & REVIEW DISCIPLINE INITIAL COMMENTS

At the initial phase of the review, the Division of Nonprescription Drugs I (DNPD I) provided comments for consideration as part of the misbranding assessment of the proposed proprietary name. The Division of Nonprescription Drugs I (DNPD I) did not provide misbranding concerns

and determined that Mucinex 12 HR Cold & Fever Multi-Symptom would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of DNPD I's assessment for Mucinex 12 HR Cold & Fever Multi-Symptom.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom.

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

RB indicated in their submission that the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, is an extension of the Mucinex brand, which is well known for upper respiratory relief, and the proposed proprietary name helps consumers to differentiate it from other Mucinex extended-release tablets when selecting products.

This proprietary name is comprised of multiple words, the root name, Mucinex, and the modifier, "12 HR Cold & Fever Multi-Symptom."

2.2.3 FDA NAME SIMULATION STUDIES

Seventy-seven practitioners participated in DMEPA's prescription studies for Mucinex 12 HR Cold & Fever Multi-Symptom.

Two participants from the inpatient (n=1) and outpatient (n=1) name simulation studies omitted the word "Multi-Symptom" in the modifier "12 HR Cold & Fever Multi-Symptom" and responded with "Mucinex 12 HR Cold & Fever." In this instance, no "Mucinex 12 HR Cold & Fever" product is marketed. Thus, users would likely receive the Mucinex 12 HR Cold & Fever Multi-Symptom product, and the residual risk of name confusion is acceptable in this case.

The remaining 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.

2.2.4 EVALUATION OF THE ROOT NAME, MUCINEX

The root name, Mucinex, has been the proprietary name for guaifenesin extended-release tablets since its approval on July 12, 2002, for the nonprescription indication as an expectorant: to help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. RB stated in the submission that "Mucinex" in the Mucinex product line consists of a range of products containing guaifenesin,

[d] USAN stem search conducted on February 1, 2024.

which relieves chest congestion. The proposed product contains the active ingredient guaifenesin and the first bullet in the proposed DFL *Uses* is the same expectorant indication:

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Additionally, our routine post-marketing surveillance of nonprescription drug products has not identified name confusion medication error concerns associated with Mucinex that warrants regulatory action. Therefore, we find the use of the root name, Mucinex, acceptable.

2.2.5 EVALUATION OF THE MODIFIER, COLD & FEVER MULTI-SYMPTOM

In addition to the active ingredient guaifenesin, the proposed product contains the additional active ingredients, naproxen sodium and dextromethorphan hydrobromide. RB stated in the submission that "Cold & Fever" points to the combined active ingredients, i.e., dextromethorphan bromide and naproxen sodium, and their approved indications. The proposed DFL *Uses* include the indications for dextromethorphan bromide, which are:

- temporarily relieves: cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants, the intensity of coughing, the impulse to cough to help you get to sleep.

And the proposed DFL *Uses* include several of the indications for naproxen sodium as it relates to upper respiratory symptoms, pain, and fever:

- temporarily relieves minor aches and pains due to headache and the common cold and temporarily reduces fever.

Moreover, the use of "Cold" is already used in nonprescription nomenclature of currently marketed application products (e.g., Advil Cold and Sinus) to describe an indication of use, and we are not aware of name confusion concerns associated with the modifier "Cold" from our routine post-marketing surveillance of nonprescription drug products.

The use of "Fever" is novel in nonprescription nomenclature for application products. However, for the proposed product, the use of "Fever" accurately reflects the active ingredient naproxen and its proposed indication to relieve minor aches and pains and fever.

RB stated that "Multi-Symptom" points to the three active ingredients, which provides relief for multiple symptoms, including cough, minor aches and pain, and fever. Additionally, "Multi-Symptom" is already used in nonprescription nomenclature of currently marketed application products (e.g., Advil Multi-Symptom Cold & Flu and Imodium Multi-Symptom Relief) to describe a combination of multiple active ingredients and their respective indications of use. Also, we are not aware of name confusion concerns associated with the modifier "Multi-Symptom" from our routine post-marketing surveillance of nonprescription drug products.

The proposed product contains three active ingredients, and we find that the proposed modifier "Cold & Fever Multi-Symptom" in the proposed proprietary name, Mucinex 12 HR

Cold & Fever Multi-Symptom, suggests the name of all the active ingredients in the proposed product (per 21 CFR 201.6(b)).[e]

Therefore, based on the aforementioned reasons, we find the use of the proposed modifier "Cold & Fever Multi-Symptom" acceptable.

2.2.6 EVALUATION OF THE MODIFIER, 12 HR

RB stated in the submission that the proposed product is an extended-release formulation, dosed every 12 hours, whereby the use of "12 HR" in the proposed proprietary name differentiates it from immediate-release formulations that are dosed every 4 hours. The acceptability of "12 HR" in the proposed proprietary name is dependent on the overall review and appropriateness of the proposed product's 12-hour dosing interval, which is still ongoing. We reminded RB at the December 6, 2023 teleconference of the review issue related to the 12-hour dosing interval. Therefore, at this time, acceptability of "12 HR" in the proposed proprietary name remains a review issue and is contingent on the review team's determination of the 12-hour dosing interval.

2.2.7 COMMUNICATION OF DMEPA 2'S DETERMINATION

On March 8, 2024, DMEPA 2 communicated our determination to the Division of Nonprescription Drugs I (DNPDI).

3 CONCLUSION

The proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, is conditionally acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO RB HEALTH US LLC

We have completed our review of the proposed proprietary name, Mucinex 12 HR Cold & Fever Multi-Symptom, and have concluded that this proprietary name is conditionally acceptable.

If any of the proposed product characteristics as stated in your submission (e.g., the proposed 12-hour dosing interval), received on December 19, 2023, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review. Please note the proposed 12-hour dosing interval is still under review.

[e] See (21 CFR 201.6(b)) (labeling for a drug containing two or more ingredients may be misleading if the name of the drug designated in that labeling includes or suggests the name of one or more but not all of the ingredients).

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3*. 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]

*Table 3. 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?

[f] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. 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.	
	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. FDA Prescription Simulation Studies: DMEPA also conducts 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.

c. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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.

   Additionally, other review disciplines opinions such as OPQ 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 Safety Evaluator 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.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Mucinex 12 HR Cold & Fever Multi-Symptom Study (Conducted on 2/9/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order: Mucinex 12 HR Cold & Fever Multi-Symptom 2 tablets po q 12 hrs	Mucinex 12 HR Cold & Fever Multi-Symptom Take 2 tablets by mouth every 12 hours Dispense 8
Outpatient Prescription: Mucinex 12HR Cold & Fever Multi-Symptom Take 2 tablets PO every 12 hours # 8	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Mucinex 12 HR Cold & Fever Multi-Symptom	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Mucinex 12 HR Cold & Fever Multi-Symptom People Received Study: 165 People Responded: 78					
Total	18	22	15	23	78
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MUCINEX 12 H COLD AND FEVER MULTISYMPTOMS	0	0	1	0	1
MUCINEX 12 HOUR COLD & FEVER MULTI SYMPTOM	1	1	0	0	2
MUCINEX 12 HOUR COLD & FEVER MULTI-SYMPTOM	0	3	2	0	5
MUCINEX 12 HOUR COLD AND FEVER MULTI SYMPTOM	0	0	2	0	2
MUCINEX 12 HOUR COLD AND FEVER MULTISYMPTOM	0	0	1	0	1
MUCINEX 12 HOUR COLD AND FEVER MULTI-SYMPTOM	1	1	2	0	4
MUCINEX 12 HR COLD & FEVER	0	1	0	0	1
MUCINEX 12 HR COLD & FEVER MULTI - SYMPTOM	1	0	0	0	1

MUCINEX 12 HR COLD & FEVER MULTI-SYMPTOM	0	1	0	0	1
MUCINEX 12 HR COLD & FEVER MULTISYMPTOM	1	0	0	0	1
MUCINEX 12 HR COLD & FEVER MULTI-SYMPTOM	5	5	0	0	10
MUCINEX 12 HR COLD AND FEVER MULTI SYMPTOM	0	1	0	0	1
MUCINEX 12 HR COLD AND FEVER MULTI SYMTON	1	0	0	0	1
MUCINEX 12 HR COLD AND FEVER MULTISYMPTOM	0	0	1	0	1
MUCINEX 12 HR COLD AND FEVER MULTI-SYMPTOM	5	3	0	23	31
MUCINEX 12 HR COLD AND FEVER MULTI-SYMPTOMS	1	0	0	0	1
MUCINEX 12H COLD AND FEVER MULTI-SX	0	0	1	0	1
MUCINEX 12-HOUR COLD AND FEVER MULTI SYMPTOM	0	0	1	0	1
MUCINEX 12HOUR COLD AND FEVER MULTI-SYMPTOM	0	0	1	0	1
MUCINEX 12-HOUR COLD AND FEVER MULTISYMPTOM	0	0	2	0	2
MUCINEX 12HR COLD & FEVER MULTI-SYMPTOM	1	4	0	0	5
MUCINEX 12HR COLD AND FEVER	1	0	0	0	1
MUCINEX 12HR COLD AND FEVER MULTISYMPTOM	0	0	1	0	1
MUCINEX 12HR COLD AND FEVER MULTI-SYMPTOM	0	1	0	0	1
MUCINEXT 12 HOUR COLD AND FEVER MULTI SYMPTOM	0	1	0	0	1

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

GRACE JONES
03/08/2024 03:08:42 PM

ASHLEIGH V LOWERY
03/08/2024 03:12:33 PM

CHI-MING TU
03/08/2024 04:02:11 PM

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:	November 3, 2016
Application Type and Number:	IND 105403
Product Name and Strength:	(b) (4) (Guaifenesin/ Dextromethorphan Hydrobromide/Naproxen Sodium) Extended Release Tablets, 600 mg/30 mg/110 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	OTC
Applicant/Sponsor Name:	Reckitt Benckiser LLC
Panorama #:	2016-8042888
DMEPA Primary Reviewer:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD
DMEPA Acting Associate Director:	Danielle Harris, PharmD, BCPS
DMEPA Director:	Todd Bridges, RPh

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, [redacted] (b) (4) from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Sponsor did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

On May 13, 2016, the Sponsor submitted the proposed proprietary name, [redacted] (b) (4) [redacted] (b) (4) The Sponsor stated the modifier "12" reinforces the 12 hour (twice a day) dosing regimen and it's important to differentiate this product from other immediate-release dosage forms. In response to our June 6, 2016 email correspondence recommending to include the term "hour" or the abbreviation "hr" in the proposed proprietary name so that the proposed every 12 hour dosing regimen is clearly conveyed, the Sponsor submitted an amendment on June 9, 2016 for the proposed proprietary name, [redacted] (b) (4) for review.

Table 1 provides information of NDA products within the Mucinex line.

Table 1. Approval History of Mucinex Products (from Drugs@FDA)

Drug Name/ Application No.	Active Ingredient(s)	Dosage Form	Strengths	Marketing Status	Approval Date
Mucinex (NDA 021282)	Guaifenesin	Tablet, extended release	600 mg, and 1200 mg	OTC	July 12, 2002
Mucinex D (NDA 021585)	Guaifenesin/ Pseudoephedrine HCl	Tablet, extended release	600 mg/60 mg, and 1200 mg/120 mg	OTC	June 22, 2004
Mucinex DM (NDA 021620)	Guaifenesin/ Dextromethorphan HBr	Tablet, extended release	600 mg/30 mg, and 1200 mg/60 mg	OTC	April 29, 2004

1.2 PRODUCT INFORMATION

The following product information is provided in the June 9, 2016 proprietary name submission.

- Intended Pronunciation: [redacted] (b) (4)
- Active Ingredient: Guaifenesin/Dextromethorphan Hydrobromide/Naproxen Sodium
- Indication of Use:
    - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
    - temporarily relieves: the intensity of coughing, cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants, the impulse to cough to help you get to sleep, minor aches and pains due to the common cold, headache due to the common cold
    - temporarily reduces fever

- Route of Administration: oral
- Dosage Form: extended-release tablets
- Strength: 600 mg/30 mg/110 mg
- Dose and Frequency: Adults (b) (4) years and older: take 2 tablets every 12 hours. Not to exceed 4 tablets in 24 hours. Children under (b) (4) years of age: Do not use
- How Supplied: The preliminary packaging configuration of this OTC product is currently proposed as the following: the bi-layer tablets will be enclosed in (b) (4) blister cards sealed with foil backing. An appropriate number of blister cards will be packaged into a paperboard carton.
- Storage: Store between 20-25°C (68-77°F). Avoid (b) (4) excessive heat above 40°C (104°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT & COMMENTS AT INITIAL REVIEW

At the initial phase of the review, in response to our initial OSE, May 24, 2016 email, the Division of Nonprescription Drug Products (DNDP) provided the following comments relating to the proposed proprietary name (b) (4) the proposed product uses a (b) (4)

Since the amended proposed proprietary name is (b) (4) which maintains the same modifiers that DNDP already reviewed except for the addition of the modifier, Hr, we did not send another email for misbranding comments.

We acknowledge DNDP's initial comments at the initial phase of the review. However, we determined that the proposed proprietary name, (b) (4) does not appear to misbrand the proposed product (See Sections 2.2.4 and 2.2.5). In response to our request for concurrence with our determination of the acceptability of the proposed name on November 1, 2016, DNDP did not object to the name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[a] USAN stem search conducted on August 15, 2016.

2.2.2 *Components of the Proposed Proprietary Name*

The Sponsor indicated in their submission that the proposed name, (b) (4) (b) (4)

2.2.3 *FDA Name Simulation Studies*

Sixty-eight practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Twelve practitioners responded with the correct interpretation of the proposed proprietary name, (b) (4) (b) (4); an additional 28 practitioners wrote out "and" for the ampersand, or wrote out "Hour" or "H" for "Hr" or omitted the space in "12 Hr". Appendix B contains the results from the verbal and written prescription studies.

2.2.4 *Medication Error Data Selection of Cases*

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving ***Mucinex*** that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	August 15, 2016
Drug Name	*Mucinex* [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR

	MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	None

The FAERS database search identified 54 cases. Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, 37 cases were not included in the final analysis because they did not describe name confusion with Mucinex.

Following exclusions, 17 cases of wrong drug errors remained. Table 3 lists the drug names confused with Mucinex and the number of wrong drug error cases(s) reported in each year from 2004 to June 8, 2015 (year only displays in row if a wrong drug error was reported in that year).

Table 3. Wrong drug errors due to name confusion with Mucinex

Drug Names Confused with Mucinex				
Year of initial report	**Mucomyst**	**Mucinex DM**	**Mucinex Allergy**	**Total**
2004	2			2
2005	5			5
2006	6			6
2007	1			1
2008	1			1
2011		1		1
2015			1	1
Grand Total	**15**	**1**	**1**	**17**

Fifteen of the 17 cases were reported between 2004 and 2008 and all were related to name confusion between Mucinex and Mucomyst. Of the 15 cases related to confusion between Mucinex and Mucomyst, 9 cases reported the root cause as look-alike and/or sound-alike

between Mucinex and Mucomyst. No cases reported an adverse event; however, 2 cases reported that there was a delay in the procedure that the patient was intended to receive.

One case reported in 2011 was related to name confusion between Mucinex and Mucinex DM. The case described an 82 year old patient who patient accidentally purchased Mucinex DM instead of the intended Mucinex. This 82 year old patient has a history of COPD and hepatitis C and reported prior use of Mucinex. This patient believed that the Mucinex DM contributed to his chest congestion, and reported being admitted to the hospital for one night to receive nebulizer treatments to loosen the mucous. Of note, Mucinex and Mucinex DM contain a common active ingredient guaifenesin, with Mucinex DM containing an additional active ingredient dextromethorphan. The carton labeling for Mucinex DM is differentiated from the Mucinex carton labeling.

The one remaining case reported in 2015 was related to name confusion between Mucinex and Mucinex Allergy. In this case, the reporter indicated her prescriber instructed her to take original Mucinex, and the reporter's spouse purchased Mucinex Allergy and not Mucinex. Once the reporter discovered the purchased product was different from the intended Mucinex, she discontinued the Mucinex Allergy. No other information was reported in this case. Mucinex Allergy contains the active ingredient fexofenadine and does not contain guaifenesin; however, it appears this product is no longer marketed.

Although our FAERS search retrieved cases of confusion between Mucinex and Mucomyst stemming back to 2004, no confusion has been reported between Mucinex and Mucomyst since 2008. In addition, although there were 2 cases related to confusion between Mucinex and another product within the Mucinex product line (Mucinex DM and Mucinex Allergy), the 2 cases reported during this time span of 14 years appear to be isolated occurrences. Thus, our search did not identify any ongoing name confusion between Mucinex and existing drug products, nor did we identify any ongoing name confusion between Mucinex and currently marketed OTC products. Moreover, the addition of the modifiers, 12 Hr, Cold, (b) (4) may inform consumers that the proposed product contains active ingredients in addition to guaifenesin and thus helps to differentiate these products from each other. Therefore, our assessment of the root name Mucinex did not identify any safety concerns.

2.2.5 Evaluation of the Modifiers 12 Hr, Cold, (b) (4)

The Sponsor stated the root name Mucinex refers to the Guaifenesin which relieves chest congestion by thinning and loosening mucus secretion. The Sponsor also indicated in their submission the rationale for each of the modifiers as follows:

- 12 Hr – reinforces the 12 hour (twice a day) dosing regimen, and differentiates this proposed product from immediate release dosage forms.
- Cold – relieves symptoms associated with the common cold including chest congestion, cough, fever, pain, and headaches.

(b) (4)

The use of dosing interval modifiers exist in the proprietary names of currently marketed OTC products, whereby the use of terms such as “Hr”, “hour”, and “HR” in OTC nomenclature for OTC products appear to describe a period of time. The use of the modifier “12 Hr” in naming this proposed OTC product to indicate its dosing interval of every 12 hours or twice daily appears consistent with existing OTC nomenclature for other OTC products (See Table 4). Moreover, we are not aware of any name confusion associated with the dosing interval “Hr” or “hour” from our routine postmarketing surveillance of OTC products. Thus, the modifier “12 Hr” in the proposed proprietary name, (b) (4) is acceptable.

The modifier “Cold” is already used in the nomenclature of currently marketed OTC products (See Table 5). The modifier “Cold” in OTC nomenclature for OTC products appears to describe the relief of the symptoms associated with the common cold or flu including headache, minor body aches & pain, sinus pressure, nasal and sinus congestion, and fever. The use of the modifier “Cold” in naming this proposed OTC product appears to indicate the proposed product’s uses:

- Temporarily relieves: the intensity of coughing, cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants, the impulse to cough to help you get to sleep, minor aches and pains due to the common cold, headache due to the common cold
- Temporarily reduces fever

This appears consistent with existing OTC nomenclature for other OTC products. Additionally, we are not aware of name confusion associated with the modifier “Cold” from our routine postmarketing surveillance of OTC products.

We did not identify the use of the modifiers (b) (4) in existing OTC products marketed under an application.[b] Based on the proposed use submitted in the June 9, 2016 proprietary name submission, we did not identify any risk of confusion or concern associated with the modifiers (b) (4) in the proposed proprietary name because (b) (4) (b) (4)

Given that the Sponsor will need to provide additional data to support the proposed uses for the proposed product (See DARRTS, Meeting Minutes, dated 9/10/2015) in the course of the NDA review, we do not object to the proposed proprietary name, (b) (4) (b) (4) under this IND review of the name. If DNDP determines later during NDA review that the proposed product’s uses differs from the currently proposed uses, then DMEPA will reassess the suitability of the proposed proprietary name, (b) (4)

[b] Drugs@FDA search dated 10/29/2016 and Orange Book search dated 11/2/2016 for (b) (4) did not identify any OTC products marketed with either modifier.

Table 4. Products with the modifiers HR and Hour in OTC Nomenclature (from Drugs@FDA)

Product Name	Frequency of Administration
Tylenol 8 HR Muscle Aches and Pain	Every 8 hours
Tylenol 8 HR Muscle Aches and Pain	Every 8 hours
Allegra-D 12 Hour Allergy and Congestion	Every 12 hours
Chlor-Trimeton Allergy D 12 Hour	Every 12 hours
Sudafed 12 Hour	Every 12 hours
Zyrtec-D 12 Hour	Every 12 hours
Allegra-D 24 Hour Allergy and Congestion	Once daily
Claritin-D 24 Hour	Once daily
Nasacort Allergy 24 Hour	Once daily
Nexium 24HR	Once daily
Nexium 24HR	Once daily
Sudafed 24 Hour	Once daily

Table 5. Products with the modifier Cold in OTC Nomenclature (from Drugs@FDA and DailyMed)

Product Name	Active Ingredients	Uses
Advil Cold And Sinus	Ibuprofen, Pseudoephedrine HCl	Temporarily relieves these symptoms associated with the common cold (b) (4) headache, fever, sinus pressure, nasal congestion, and minor body aches & pain.
Aleve-D Sinus & Cold	Naproxen sodium, Pseudoephedrine HCl	Temporarily relieves these cold, sinus, (b) (4) symptoms: sinus pressure, minor body aches and pains, headache, nasal and sinus congestion (promotes sinus drainage and restores freer breathing through the nose), and fever.
Children's Advil Cold	Ibuprofen, Pseudoephedrine HCl	Temporarily relieves these cold, sinus (b) (4) symptoms: nasal and sinus congestion, headache, stuffy nose, sore throat, minor aches and pains, and fever
Children's Motrin Cold	Ibuprofen, Pseudoephedrine HCl	Temporarily relieves these cold, sinus (b) (4) symptoms: nasal and sinus congestion, headache, stuffy nose, sore throat, minor body aches and pains, and fever

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Nonprescription Drug Products (DNDP) via e-mail on October 31, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNDP on November 1, 2016, they stated no additional comments or concerns with the proposed proprietary name, (b) (4)

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, (b) (4) (b) (4) and have concluded that this name is acceptable.

A request for proprietary name review for (b) (4) should be submitted once the NDA is submitted.

4 REFERENCES

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.

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).

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. [c]

[c] 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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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. 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.

c. 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.

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

Appendix B: Prescription Simulation Samples and Results

Figure 1. [redacted] (b) (4) **Study (Conducted on August 19, 2016)**

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: (b) (4) [redacted] Take 2 tablets po every 12 hours #10	
Outpatient Prescription: (b) (4) [redacted] 2 tablets po q 12 hours	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

310 People Received Study
68 People Responded

Study Name: (b) (4) [redacted]

Total	25	16	27	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
MUCINEX	2	0	3	5
(b) (4) [redacted]	0	4	1	5
	2	0	0	2
	1	0	0	1
MUCINEX 12 HR	0	0	1	1
(b) (4) [redacted]	0	1	1	2
	0	0	1	1
	1	1	1	3
	0	0	1	1
	7	0	5	12
	0	0	1	1
	0	0	2	2

(b) (4)	2	0	1	3
	4	1	2	7
	1	0	0	1
	0	1	0	1
	0	0	1	1
	0	1	0	1
	0	0	1	1
	1	0	0	1
MUCINEX 12HR	0	1	0	1
(b) (4)	0	1	0	1
	0	0	1	1
	0	2	0	2
	1	0	1	2
	1	0	0	1
	1	0	0	1
	0	0	1	1
MUCINEX 24HR	1	0	1	2
(b) (4)	0	1	0	1
	0	1	0	1
	0	0	1	1
	0	1	0	1

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GRACE JONES
11/03/2016

DANIELLE M HARRIS on behalf of CHI-MING TU
11/04/2016

DANIELLE M HARRIS
11/04/2016

TODD D BRIDGES
11/04/2016