CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761219Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	March 30, 2023
Application Type and Number:	BLA 761219
Product Name and Strength:	Yuflyma (adalimumab-aaty) Injection, (b) (4)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
PNR ID #:	2023-1044724928
DMEPA 1 Safety Evaluator:	Teresa McMillan, PharmD
DMEPA 1 Team Leader:	Idalia Rychlik, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Yuflyma, which was found conditionally acceptable under BLA 761219 on August 4, 2022.[a]

We note that there is a change in the previously submitted product characteristics, as Celltrion proposed to add the following pediatric Crohn's Disease indication and dose/frequency for pediatric patients 6 years of age and older for BLA 761219:

- *Pediatric Patients 6 Years of Age and Older*:

Pediatric Weight	**Recommended Dosage**	
	Days 1 through 15	**Starting on Day 29***
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg	40 mg every other week

(b) (4)

Thus, Celltrion submitted the name, Yuflyma, under BLA 761219 for re-review on January 9, 2023. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Yuflyma would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Yuflyma. The Division of Rheumatology and Transplant Medicine (DRTM) did not comment on the findings of OPDP's assessment for Yuflyma.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the addition of the pediatric Crohn's indication and associated dosing/frequency of administration of 160 mg on day 1 (single dose or split over two consecutive days), 80 mg on day 15, and 40 mg every other week. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Yuflyma.

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[a] McMillan, T. Proprietary Name Review for Yuflyma (BLA 761219). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 AUG 04. PNR ID No. 2022-1044724611.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The February 15, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Yuflyma.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On March 30, 2023, we communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Yuflyma, is conditionally acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO CELLTRION, INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 9, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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/s/

TERESA S MCMILLAN
03/30/2023 03:00:56 PM

IDALIA E RYCHLIK
03/30/2023 03:15:33 PM

MISHALE P MISTRY
03/31/2023 04:20:58 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	3/2/2023
Responsible OND Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761219
Product Name and Strength:	Yuflyma (adalimumab-aaty) injection 40 mg/0.4 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
Nexus NPNS ID #:	2022-158
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -aaty, for BLA 761219, which was found conditionally acceptable on August 11, 2021[a] and July 21, 2022[b], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761219.

1.1 Regulatory History

FDA found the proposed four-letter suffix, -aaty, conditionally acceptable for BLA 761219 on August 11, 2021[a]. However, BLA 761219 received a Complete Response (CR) letter on November 24, 2021[c]. Subsequently, Celltrion submitted a Class 2 Resubmission on May 27, 2022. Upon re-review we found the suffix -aaty conditionally acceptable on July 21, 2022[b]. However, BLA 761219 received a CR letter on November 23, 2022[d]. Thus, Celltrion submitted a Class 2 Resubmission on November 30, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -aaty, using the principles described in the applicable guidance[e].

We determined that the proposed suffix -aaty, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

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[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-aaty (BLA 761219). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 11. Nexus NPNS ID No.: 2020-43.

[b] Mena-Grillasca,C.M. Nonproprietary Name Suffix Review for adalimumab-aaty (BLA 761219). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 Jul 21. Nexus NPNS ID No. 2022-101.

[c] Nikolov, N.P. Complete Response (BLA 7611219). Silver Spring (MD): FDA, CDER, OND, DRTM (US); 2021 Nov 24.

[d] Nikolov, N.P. Complete Response (BLA 7611219). Silver Spring (MD): FDA, CDER, OND, DRTM (US); 2022 Nov 23.

[e] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On March 1, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM) on March 2, 2023.

4 CONCLUSION

We find the suffix -aaty acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to adalimumab-aaty. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Celltrion, Inc.

We find the nonproprietary name, adalimumab-aaty, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, adalimumab-aaty will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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/

CARLOS M MENA-GRILLASCA
03/02/2023 05:52:57 PM

MISHALE P MISTRY
03/03/2023 09:29:17 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	August 4, 2022
Application Type and Number:	BLA 761219
Product Name and Strength:	Yuflyma (adalimumab-aaty) [a] Injection, (b) (4)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
PNR ID #:	2022-1044724611
DMEPA 1 Safety Evaluator:	Teresa McMillan, PharmD
DMEPA 1 Team Leader:	Idalia Rychlik, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD

[a] The proposed nonproprietary name, adalimumab-aaty was found conditionally acceptable on July 21, 2022. We therefore refer to the proposed product as "adalimumab-aaty" throughout this review in place of the nonproprietary name for this product.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Yuflyma, 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. Celltrion did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Celltrion previously submitted the proposed proprietary name, Yuflyma*** on November 24, 2020 under BLA 751219. On February 19, 2021, we found the name, Yuflyma*** acceptable.[b]

However, BLA 761219 received a Complete Response on November 21, 2021. Celltrion resubmitted BLA 761219 on May 31, 2022 to the Agency. Thus, Celltrion resubmitted the name, Yuflyma, for review on May 31, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 31, 2022.

- Pronunciation: yoo-fly'-mah
- Nonproprietary Name: adalimumab-aaty
- Indication: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: (b) (4)
- Dose and Frequency:

  Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis:
  - 40 mg every other week.
  - Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

  Juvenile Idiopathic Arthritis:
  - Greater than or equal to 30 kg (66 lbs): 40 mg every other week

  Adult Crohn's Disease and Ulcerative Colitis:
  - Initial dose (Day 1): 160 mg
  - Second dose two weeks later (Day 15): 80 mg
    Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week.

[b] McMillan, T. Proprietary Name Review for Yuflyma (BLA 761219). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 FEB 19. PNR ID No. 2020-44044790.

For patients with Ulcerative Colitis only: Only continue Yuflyma in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.

Plaque Psoriasis:

- 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose

- How Supplied: YUFLYMA (adalimumab-xxxx) is supplied as a preservative-free, sterile, clear to opalescent, and colorless to pale brown solution for subcutaneous administration. The following packaging configurations are available.

YUFLYMA AI Carton - 40 mg/0.4 mL 1 pack

YUFLYMA is supplied in a carton containing two alcohol preps and a single-dose prefilled autoinjector, containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

YUFLYMA AI Carton - 40 mg/0.4 mL 2 pack

YUFLYMA is supplied in a carton containing two alcohol preps and two single-dose prefilled autoinjectors, each containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

YUFLYMA AI Carton - 40 mg/0.4 mL 4 pack

YUFLYMA is supplied in a carton containing four alcohol preps and four single-dose prefilled auto-injectors, each containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

YUFLYMA AI Carton - 40 mg/0.4 mL 6 pack

YUFLYMA is supplied in a carton containing six alcohol preps and six single-dose prefilled autoinjectors, each containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 1 pack

YUFLYMA is supplied in a carton containing two alcohol preps and a single-dose prefilled syringe with safety guard, 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 2 pack

YUFLYMA is supplied in a carton containing two alcohol preps and two single-dose prefilled syringes with safety guard, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 4 pack

YUFLYMA is supplied in a carton containing four alcohol preps and four single-dose prefilled syringes with safety guard, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 6 pack

YUFLYMA is supplied in a carton containing six alcohol preps and six single-dose prefilled syringes with safety guard, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

Prefilled Syringe Carton - 40 mg/0.4 mL 1 pack

YUFLYMA is supplied in a carton containing two alcohol preps and a single-dose prefilled syringe, 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4).

Prefilled Syringe Carton - 40 mg/0.4 mL 2 pack

YUFLYMA is supplied in a carton containing two alcohol preps and two single-dose prefilled syringes, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4).

Prefilled Syringe Carton - 40 mg/0.4 mL 4 pack

YUFLYMA is supplied in a carton containing four alcohol preps and four single-dose prefilled syringes, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

Prefilled Syringe Carton - 40 mg/0.4 mL 6 pack

YUFLYMA is supplied in a carton containing six alcohol preps and six single-dose prefilled syringes, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is (b) (4)

- Storage: Do not use beyond the expiration date on the container. YUFLYMA must be refrigerated at 36°F to 46°F (2°C to 8°C). DO NOT FREEZE. Do not use if frozen even if it has been thawed.

  Store in original carton until time of administration to protect from light.

  If needed, for example when traveling, YUFLYMA may be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 30 days, with protection from light. YUFLYMA should be discarded if not used within the 30-day period. Record the date when YUFLYMA is first removed from the refrigerator in the spaces provided on the carton and dose pack. Do not store YUFLYMA in extreme heat or cold.

(b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

Rheumatology and Transplant Medicine (DRTM) concurred with the findings of OPDP's assessment for Yuflyma.

2.2 SAFETY ASSESSMENT

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

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

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On June 22, 2022, the Division of Rheumatology and Transplant Medicine (DRTM) did not forward any comments or concerns relating to Yuflyma at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Two hundred and sixty-two practitioners participated in DMEPA's prescription studies for Yuflyma. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 17 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two names not previously analyzed. These names are included in Table 1 below.

[c] USAN stem search conducted on July 11, 2022.

[d] POCA search conducted on July 11, 2022 in version 4.5.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2
Low similarity name pair: combined match percentage score ≤54%	0

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

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

2.2.8 Communication of DMEPA's Determination

On August 4, 2022, DMEPA 1 communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

3 CONCLUSION

The proposed proprietary name, Yuflyma, is acceptable.

If you have any questions or need clarifications, please contact Davis Mathews, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO CELLTRION, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 31, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

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

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

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

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

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

- Low similarity: combined match percentage score ≤54%.

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

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

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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

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

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

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

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

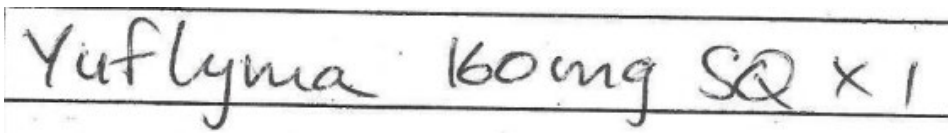
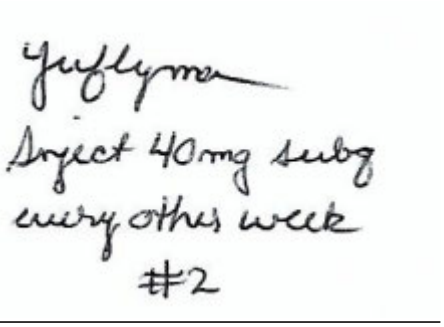
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Yuflyma Study (Conducted on June 24, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Yuflyma Inject 40 mg subq every other week #2
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Yuflyma	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
100 People Responded

Study Name: Yuflyma

Total	**29**	**25**	**17**	**29**	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
EUFLYMA	**0**	**0**	**1**	**0**	**1**
MUFLYMA	**0**	**0**	**1**	**0**	**1**
NUFLYMA	**0**	**0**	**3**	**0**	**3**
UFLIMA	**0**	**0**	**1**	**0**	**1**
UFLYMA	**0**	**0**	**8**	**0**	**8**
UVLYMA	**0**	**0**	**1**	**0**	**1**
YEFLYMA	**0**	**0**	**0**	**1**	**1**
YERFLYMA	**0**	**0**	**0**	**1**	**1**
YLLYMEA	**0**	**0**	**0**	**1**	**1**
YUFLIMA	**0**	**0**	**1**	**0**	**1**
YUFLYMA	**25**	**25**	**1**	**23**	**74**
YUFLYME	**0**	**0**	**0**	**1**	**1**
YUFLYMER	**0**	**0**	**0**	**1**	**1**
YUFLYMO	**0**	**0**	**0**	**1**	**1**
YUFLYNIA	**4**	**0**	**0**	**0**	**4**

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

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

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

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

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

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

No.	Name	POCA Score (%)
1.	Posluma***	58
2.	(b) (4) ***	56

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

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/s/

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IDALIA E RYCHLIK
08/05/2022 09:55:12 AM

MISHALE P MISTRY
08/05/2022 04:21:18 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	7/21/2022
Responsible OND Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761219
Product Name and Strength:	Yuflyma (adalimumab-aaty) injection 40 mg/0.4 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
Nexus NPNS ID #:	2022-101
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Division Director:	Irene Z Chan, PharmD, BCPS

1 PURPOSE OF REVIEW

This review is to reassess the FDA-generated suffix, -aaty, for BLA 761219, which was found conditionally acceptable on August 11, 2021[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761219.

1.1 Regulatory History

The proposed four-letter suffix, -aaty, was found conditionally acceptable for BLA 761219 on August 11, 2021[a]. However, BLA 761219 received a Complete Response (CR) letter on November 24, 2021[b]. Thus, Celltrion submitted a Class 2 Resubmission on May 27, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -aaty, using the principles described in the applicable guidance[c].

We determined that the proposed suffix -aaty, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On July 20, 2022, OPDP did not identify any concerns that would render this suffix unacceptable. DMAMES also communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM) on July 21, 2022.

---

[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for adalimumab-aaty (BLA 761219). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 11. Nexus NPNS ID No.: 2020-43.

[b] Nikolov, N. Complete Response (BLA 761219). Silver Spring (MD): FDA, CDER, OND, DRTM (US); 2021 Nov 24.

[c] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4 CONCLUSION

We find the suffix -aaty acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to adalimumab-aaty. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Celltrion, Inc.

We find the nonproprietary name, adalimumab-aaty, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, adalimumab-aaty will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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/s/

CARLOS M MENA-GRILLASCA
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IRENE Z CHAN
07/22/2022 05:04:23 PM
Signed on behalf of Mishale Mistry

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	8/11/2021
Responsible OND Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761219
Product Name and Strength:	Yuflyma (adalimumab-aaty) injection, 40 mg/0.4 mL
Product Type:	Combination Product (Drug-Biologic)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
FDA Received Date:	November 24, 2020
Nexus NPNS ID #:	2020-43
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Celltrion for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761219.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On November 24, 2020, Celltrion submitted a list of 5 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Celltrion also provided findings from their evaluation of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Celltrion:

Table 1. Suffixes submitted by Celltrion***	
1.	(b) (4)
2.	
3.	aaty
4.	(b) (4)
5.	

We reviewed Celltrion's proposed suffixes in the order of preference listed by Celltrion, along with the supporting data they submitted, using the principles described in the applicable guidance.[b]

(b) (4)

[a] Non-Proprietary Name BLA 761219. Incheon (Republic of Korea): Celltrion, Inc.; 2020 Nov 24. Available from: \\CDSESUB1\evsprod\bla761219\0001\m1\us\nonproprietary-name.pdf

[b] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

2.3 adalimumab-aaty

Celltrion's third proposed suffix, -aaty, is comprised of 3 distinct letters (a, t, y). We note that the letters 'aa' in the suffix represent the medical abbreviation for 'of each' and 'affected area'. We considered whether the inclusion of the letters 'aa' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -aaty, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is

devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMAMES' ANALYSIS

These findings were shared with OPDP. On August 11, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMAMES also communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM) on August 11, 2021.

4 CONCLUSION

We find Celltrion's proposed suffix -aaty acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to adalimumab-aaty. DMAMES will communicate our findings to the Applicant via letter.

4.1 Recommendations for Celltrion, Inc.

We find the nonproprietary name, adalimumab-aaty, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, adalimumab-aaty will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

We also note that the first 2 proposed suffixes are unacceptable for the following reasons:

(b) (4)

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/s/

CARLOS M MENA-GRILLASCA
08/11/2021 12:30:47 PM

LUBNA A MERCHANT
08/11/2021 12:36:22 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)

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****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.****

Date of This Review:	February 19, 2021
Application Type and Number:	BLA 761219
Product Name and Strength:	Yuflyma (adalimumab-xxxx)[a] Injection, 40 mg/0.4 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion Inc. (Celltrion)
Panorama/PNR ID #:	2020-44044790
DMEPA Safety Evaluator:	Teresa McMillan, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "adalimumab-xxxx" throughout this review in place of the nonproprietary name for this product.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Yuflyma, 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. Celltrion did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 24, 2020.

- Intended Pronunciation: yoo-fly'-mah
- Nonproprietary Name: adalimumab-xxxx
- Indication of Use: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 40 mg/0.4 mL
- Dose and Frequency:

  Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis:
  - 40 mg every other week.
  - Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

  Juvenile Idiopathic Arthritis:
  - Greater than or equal to 30 kg (66 lbs): 40 mg every other week

  Adult Crohn's Disease and Ulcerative Colitis:
  - Initial dose (Day 1): 160 mg
  - Second dose two weeks later (Day 15): 80 mg
    Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week.
    For patients with Ulcerative Colitis only: Only continue Yuflyma in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.

  Plaque Psoriasis:
  - 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose

- How Supplied: YUFLYMA (adalimumab-xxxx) is supplied as a preservative-free, sterile, clear to opalescent, and colorless to pale brown solution for subcutaneous administration. The following packaging configurations are available.

  YUFLYMA Autoinjector Carton - 40 mg/0.4 mL 1 pack

  YUFLYMA is supplied in a carton containing two alcohol preps and a single-dose prefilled autoinjector, containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch

needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

YUFLYMA Autoinjector Carton - 40 mg/0.4 mL 2 pack

YUFLYMA is supplied in a carton containing two alcohol preps and two single-dose prefilled autoinjectors, each containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

YUFLYMA Autoinjector Carton - 40 mg/0.4 mL 4 pack

YUFLYMA is supplied in a carton containing four alcohol preps and four single-dose prefilled auto-injectors, each containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

YUFLYMA Autoinjector Carton - 40 mg/0.4 mL 6 pack

YUFLYMA is supplied in a carton containing six alcohol preps and six single-dose prefilled autoinjectors, each containing a 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 1 pack

YUFLYMA is supplied in a carton containing two alcohol preps and a single-dose prefilled syringe with safety guard, 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 2 pack

YUFLYMA is supplied in a carton containing two alcohol preps and two single-dose prefilled syringes with safety guard, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 4 pack

YUFLYMA is supplied in a carton containing four alcohol preps and four single-dose prefilled syringes with safety guard, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe with Safety Guard Carton - 40 mg/0.4 mL 6 pack

YUFLYMA is supplied in a carton containing six alcohol preps and six single-dose prefilled syringes with safety guard, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe Carton - 40 mg/0.4 mL 1 pack

YUFLYMA is supplied in a carton containing two alcohol preps and a single-dose prefilled syringe, 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, providing 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe Carton - 40 mg/0.4 mL 2 pack

YUFLYMA is supplied in a carton containing two alcohol preps and two single-dose prefilled syringes, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe Carton - 40 mg/0.4 mL 4 pack

YUFLYMA is supplied in a carton containing four alcohol preps and four single-dose prefilled syringes, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

Prefilled Syringe Carton - 40 mg/0.4 mL 6 pack

YUFLYMA is supplied in a carton containing six alcohol preps and six single-dose prefilled syringes, each containing 1 mL prefilled syringe with a fixed thin wall, ½ inch needle, and 40 mg/0.4 mL of YUFLYMA. The NDC number is XXXX-XXXX-XX.

- Storage: Do not use beyond the expiration date on the container. YUFLYMA must be refrigerated at 36°F to 46°F (2°C to 8°C). DO NOT FREEZE. Do not use if frozen even if it has been thawed.

  Store in original carton until time of administration to protect from light.

  If needed, for example when traveling, YUFLYMA may be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 30 days, with protection from light. YUFLYMA should be discarded if not used within the 30-day period. Record the date when YUFLYMA is first removed from the refrigerator in the spaces provided on the carton and dose pack. Do not store YUFLYMA in extreme heat or cold.

(b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Yuflyma would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Rheumatology and Transplant Medicine (DRTM) concurred with the findings of OPDP's assessment for Yuflyma.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On December 15, 2020, the Division of Rheumatology and Transplant Medicine (DRTM) did not forward any comments or concerns relating to Yuflyma at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-one practitioners participated in DMEPA's prescription studies for Yuflyma. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 13 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

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

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	12
Low similarity name pair: combined match percentage score ≤54%	0

[b] USAN stem search conducted on December 14, 2020.

[c] POCA search conducted on December 14, 2020 in version 4.3.

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

Our analysis of the 13 names contained in Table 1 determined none of the names will pose a risk for confusion with Yuflyma as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM). At that time we also requested additional information or concerns that could inform our review. The Division of Rheumatology and Transplant Medicine (DRTM) stated no additional concerns with the proposed proprietary name, Yuflyma.

3 CONCLUSION

The proposed proprietary name, Yuflyma, is acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO CELLTRION INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 24, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [d]

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

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

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

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

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

- Low similarity: combined match percentage score ≤54%.

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

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

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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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

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

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

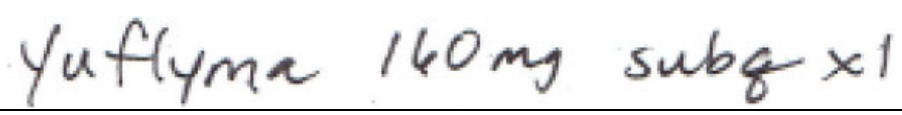
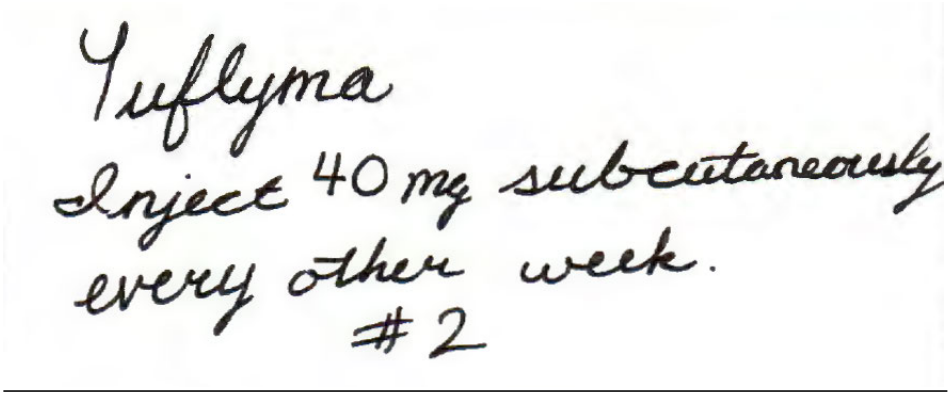
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Yuflyma Study (Conducted on December 21, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Yuflyma Inject 40 mg subcutaneously every other week #2
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Yuflyma	

FDA Prescription Simulation Responses (<u>Aggregate Report)</u>

209 People Received Study

71 People Responded

Study Name: Yuflyma

Total	13	22	12	24	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
EUFLYMA	0	0	6	0	6
EUPHLYMA	0	0	1	0	1
TUFLYMA	7	0	0	0	7
UFLIMA	0	0	1	0	1
UFLYMA	0	0	2	0	2
UFLYMA INJECTION	0	0	1	0	1
YUFLYMA	6	22	0	22	50
YUFLYMA 160 MG	0	0	0	1	1
YUFLYME	0	0	0	1	1
YUPHLIMA	0	0	1	0	1

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

No.	**Proposed name:** Yuflyma **Established name:** adalimumab-xxxx **Dosage form:** Injection **Strength(s):** 40 mg/0.4 mL **Usual Dose:** [f]	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Yuflyma***	100	This proposed proprietary name is the subject of this review.

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

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

No.	**Proposed name:** Yuflyma **Established name:** adalimumab-xxxx **Dosage form:** Injection **Strength(s):** 40 mg/0.4 mL **Usual Dose:** [f]	**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.	Yuvafem	58	This name pair has sufficient orthographic and phonetic differences.

[f] Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis:
- 40 mg every other week.
- Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

Juvenile Idiopathic Arthritis:
- Greater than or equal to 30 kg (66 lbs): 40 mg every other week

Adult Crohn's Disease and Ulcerative Colitis:
- Initial dose (Day 1): 160 mg
- Second dose two weeks later (Day 15): 80 mg
  Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week.
  For patients with Ulcerative Colitis only: Only continue Yuflyma in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy.

Plaque Psoriasis:
- 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose

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

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.	(b) (4)***	61	Proposed proprietary name withdrawn by the Applicant under NDA 211964 . NDA 211964 received a CR on November 6, 2020 under the conditionally approved proprietary name, Qelbree.
2.	Lufyllin	60	Brand discontinued with no generic equivalents available.
3.	Lufyllin-400	60	Brand discontinued with no generic equivalents available.
4.	Vanflyta***	56	Proposed proprietary name found conditionally acceptable (b) (4)

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

No.	Name	POCA Score (%)
1.	Ashlyna	59
2.	Acoflam	58
3.	Xofluza	57
4.	Falmina	56
5.	Fulyzaq	55
6.	Meflam	55
7.	Myplifa	55

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

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TERESA S MCMILLAN
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