

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211733Orig1s000

PROPRIETARY NAME REVIEW(S)

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

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

Date of This Review:	April 30, 2019
Application Type and Number:	NDA 211733
Product Name and Strength:	Advil Dual Action with Acetaminophen (Ibuprofen/Acetaminophen) Tablets, 125 mg/250 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Over-the-counter (OTC)
Applicant/Sponsor Name:	Pfizer Inc. (Pfizer)
Panorama #:	2019-29122978
DMEPA Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Advil Dual Action with Acetaminophen, 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. Pfizer did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Pfizer previously submitted the proposed proprietary name, Advil Dual Action with Acetaminophen for ibuprofen/acetaminophen, tablets, 125 mg/250 mg, under IND 112538, on May 16, 2016. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Advil Dual Action with Acetaminophen, conditionally acceptable on October 28, 2016.^a

Pfizer resubmitted the name, Advil Dual Action with Acetaminophen, for review on February 5, 2019, under NDA 211733.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 5, 2019.

- Intended Pronunciation: Advil \ 'ad-(,)vil\ Dual \dü(-e)l\ Action \ 'ak-shən\ With \ 'with\ Acetaminophen \ ə-, sē-tə-'minə-fən\

Established Name	Acetaminophen; Ibuprofen
Prescription Status	Over-the-counter (OTC)
Dosage Form(s)	Tablets
Product Strength(s)	125 mg ibuprofen / 250 mg acetaminophen
Proposed Indication(s) for Use	- Temporarily relieves minor aches and pains due to: - Headaches - Toothache - Backache - Menstrual cramps (b) (4) - Muscular aches - Minor pain of arthritis (b) (4)
Route(s) of Administration	Oral

^aJones G. Proprietary Name Review for Advil Dual Action with Acetaminophen (IND 112538). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 OCT 28. Panorama No. 2016-7989688.

Usual Dosage, Frequency of Administration, Dosing Interval, Maximum Daily Dose	2 tablets (250 mg ibuprofen / 500 mg acetaminophen); every 8 hours while symptoms persist; do not take more than (b) (4) caplets in 24 hours
Dosing in Specific Population	- Adults and children 12 years and over - Children under 12 years: ask a doctor
(b) (4)	Do not take more than directed (b) (4) - Adults and children 12 years and over: take 2 tablets every 8 hours while symptoms persist - Do not exceed 6 tablets in 24 hours unless directed by a doctor - Children under 12 years: ask a doctor
Storage Requirement	Store at 20-25°C (68-77°F). Avoid excessive heat.
How Supplied and Packaging Configuration	To be determined

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Advil Dual Action with Acetaminophen.

2.1 MISBRANDING ASSESSMENT AND INITIAL COMMENTS

At the initial phase of the review, in response to our initial OSE, February 11, 2019 email, the Division of Nonprescription Drug Products (DNPD) had no concerns relating to the proposed proprietary name, Advil Dual Action with Acetaminophen. DMEPA concurs with DNPD's assessment at initial review and concludes that the proposed proprietary name, Advil Dual Action with Acetaminophen, would not misbrand the proposed product.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Advil Dual Action with Acetaminophen.

2.2.1 United States Adopted Names (USAN) Search

DMEPA previously identified the USAN stem -io- in the proposed proprietary name, Advil Dual Action with Acetaminophen in our previous proprietary name review under IND 112538. However, we had no expectation that the word "Action" would be spelled differently to avoid containing a USAN stem. Therefore, we did not object to the proposed name. In addition, beginning in March 19, 2018, we no longer deny proposed proprietary names that contain a two-letter stems.^b

^b USAN stem search conducted on March 1, 2019.

2.2.2 Components of the Proposed Proprietary Name

Pfizer indicated in their submission that the proposed proprietary name, Advil Dual Action with Acetaminophen, is a line extension using the currently marketed root name Advil with additional modifiers, Dual Action with Acetaminophen. The root name Advil is intended to communicate that the proposed product contains ibuprofen, and the modifiers, Dual Action with Acetaminophen, are intended to communicate that the product contains an additional active ingredient, acetaminophen. Pfizer further indicated that the word, “Dual” may be defined as “consisting of two parts of elements,” “Action” may be defined as “an operating mechanism,” and “with” may be defined as “used as a function word to indicate combination, accompaniment, presence, or addition,” which communicates that the 2 active ingredients are from different pharmacologic classes and have different mechanisms of action. This proprietary name is comprised of multiple words, the root name, Advil, and the modifiers, Dual Action with Acetaminophen. We previously evaluated use of the root name and modifiers in the previous proprietary name review and maintain our previous decision.

2.2.3 FDA Name Simulation Studies

Sixty-one practitioners participated in DMEPA’s prescription studies for Advil Dual Action with Acetaminophen. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Nonprescription Drug Products (DNBP) via e-mail on April 8, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNBP on April 12, 2019, they expressed concerns with the proposed proprietary name. On April 30, 2019, we discussed with DNBP their concerns surrounding the proposed proprietary name and subsequently determined that the proposed proprietary name, Advil Dual Action with Acetaminophen, is conditionally acceptable.

3 CONCLUSION

The proposed proprietary name, Advil Dual Action with Acetaminophen, 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 PFIZER INC.

We have completed our review of the proposed proprietary name, Advil Dual Action with Acetaminophen, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on February 5, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns based on the draft Guidance for Industry entitled Best Practices in Developing Proprietary Names for Drugs available at:

<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf>

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

USAN Stems List contains all the recognized USAN stems.

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.

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. Advil Dual Action with Acetaminophen Study (Conducted on February 25, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Advil Dual Action with Acetaminophen</i> <i>2 tabs po q 8 hrs.</i>	Advil Dual Action with Acetaminophen Take 2 tablets by mouth every 8 hours Dispense 1 bottle
<u>Outpatient Prescription:</u> <i>Advil Dual Action with Acetaminophen</i> <i>2 tabs po q 8h</i> <i>#1 bottle</i>	

FDA Prescription Simulation Responses (Aggregate Report)

301 People Received Study

61 People Responded

Study Name: Advil Dual Action with Acetaminophen

Total	21	18	22	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ADVIL DUAL ACTINO WITH ACETAMINOPHEN	1	0	0	1
ADVIL DUAL ACTION	1	0	2	3
ADVIL DUAL ACTION ACETAMINOPHEN	0	1	0	1
ADVIL DUAL ACTION W/ ACETAMINOPHEN	0	0	1	1
ADVIL DUAL ACTION WITH ACETAMINOPHEN	17	13	17	47
ADVIL DUAL ACTION WITH ACETAMIONPHEN	1	0	0	1
ADVIL DUAL ACTION WITH ACETOMINOPHEN	0	2	0	2
ADVIL DUAL ACTION WITH APAP	0	2	1	3
ADVIL WITH ACETAMINOPHEN	1	0	0	1
ADVIL/ACTAMINOPHEN	0	0	1	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
04/30/2019 04:51:12 PM

CHI-MING TU
04/30/2019 05:16:46 PM

DANIELLE M HARRIS
05/02/2019 08:25:53 AM