

Lisa Myslinski PharmD

Sole Proprietor of Patent No. US 10,124,005 B1

(b)
(6)

August 23, 2019

Via Electronic Filing

Division of Dockets Management

Food and Drug Administration

Department of Health and Human Services

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Citizens Petition

I, Lisa Myslinski Pharm D., submit this petition under 21 C.F.R. §§ 10.20 and 10.30 to request that the Food and Drug Administration (FDA) amend the tentative final monograph of Acetaminophen and Caffeine to include Meclizine. The dosage of Meclizine is 6.25mg in the patent no., listed above, which would be included in this amendment. This would require the Meclizine dosage of 6.25mg to be amended in the final monograph for Meclizine under 336.10(d). Meclizine is listed under the antiemetic monograph 336.10(d). Acetaminophen and Caffeine are listed as internal analgesics under FR Citation 58 FR 28281. The dosages of Acetaminophen is 250mg and caffeine 60mg are already within the dosage ranges listed in the tentative final monograph under FR Citation 58 FR 28281.

A. Action Requested

I, Lisa Myslinski Pharm D., sole proprietor of patent no. US 10,124,005 B1; which includes Acetaminophen 250mg, Caffeine 60mg, and Meclizine 6.25mg, request that the FDA amend the tentative final monograph of Acetaminophen and Caffeine FR Citation 58 FR 28281 to include the final monograph of meclizine 336.10(d) which would include 6.25mg of Meclizine per amendment request above.

B. Statement of Grounds

Patent no. US 10,124,005 B1, issued November 13th, 2018 is a MultiSymptom Migraine Combination Medication for over-the-counter (OTC) use. It contains Acetaminophen (250mg), Caffeine (60mg), and Meclizine (6.25mg). It treats pain and nausea/vomiting. Acetaminophen is the pain reliever. Caffeine increases the pain-relieving effects of acetaminophen. Meclizine treats nausea and vomiting. More than 38 million people suffer from migraines in the United States;

73% suffer from nausea and 29% suffer from vomiting (<https://migraine.com/migraine-statistics/>). These statistics support the proposed amendment to the FDA to combine these three drugs. 21 CFR 330.10(a)(4)(iv), states that; An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant portion of the target population.

There are no drug interactions between the three medications Acetaminophen, Caffeine, and Meclizine per LexiComp and Facts & Comparisons, which are accurate drug resource platforms for many healthcare professionals. Additionally, I, Lisa Myslinski am a registered Pharmacist in the state of Illinois for over 22 years and a migraine sufferer myself. I have personally used this combination of medications with great relief and effectiveness. I have also recommended this combination of medications to my patients; which currently must be bought separately, with great success. This cumulative success over many years along with the following studies I will provide, support the amendment set forth in this petition.

Supporting Studies for Amendment

Efficacy and Safety of Acetaminophen in the Treatment of Migraine

Results of a Randomized, Double-blind, Placebo-Controlled, Population-Based Study

<https://www.jamanetwork.com/journals/jamainternalmedicine/fullarticle/747523>

Paracetamol (Acetaminophen) with or without an antiemetic for acute migraine headaches in adults.

<https://www.ncbi.nlm.gov/pubmed/21069700>

Caffeine accelerates absorption and enhances the analgesic effect of acetaminophen.

<https://www.ncbi.nlm.nih.gov/m/pubmed/17442681/>

Meclizine and Placebo in treating Vertigo of Vestibular Origin

Relative Efficacy in a Double-Blind Study

<https://jamanetwork.com/journals/jamaneurology/article-abstract/571539>

Severe and Acute Migraines: Coping with Vertigo and Nausea

<https://www.healthline.com/migraine/severe-acute-migraines-vertigo-nausea>

Vestibular Migraines

<https://www.webmd.com/migraines-headaches/vestibular-migraines#1>

Medication

Can Medication Help Me Feel Better

<https://vestibular.org/understanding-vestibular-disorders/treatment/vestibular-medications#>

Konkel, L and Weatherspoon, D. (2017). Migraine-Associated Vertigo and Nausea in Adults and Children. [online] Healthline. Available at: <https://www.healthline.com/migraine/severe-acute-migraines-vertigo-nausea>

C. Environmental Impact

An environmental assessment is not required under 21 C.F.R. § 25.31.

D. Economic Impact

An economic impact statement will be submitted at the request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Lisa Myslinski

Digitally signed by Lisa Myslinski
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Lisa Myslinski Pharm D.

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