FDA U.S. FOOD & DRUG ADMINISTRATION

Lisa Myslinksi, PharmD
(b) (6) [redacted]

May 18, 2023

Re: Docket No. FDA-2019-P-4003

Dear Dr. Myslinksi:

This letter responds to your citizen petition received on August 26, 2019 (Petition), requesting that the Food and Drug Administration (FDA or the Agency): (1) Amend 21 CFR 336.10 to permit a 6.25 mg dosage of meclizine; and (2) "amend the tentative final monograph of Acetaminophen and Caffeine" to "include the final monograph of meclizine 336.10(d) which would include 6.25 mg of Meclizine…" (Petition at 1).

We have carefully considered your Petition. For the reasons described below, your Petition is denied.

While your Petition was pending with the Agency, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted,[1] adding section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h), which changed certain aspects of the legal framework for nonprescription drug products marketed without an approved application. As a result of the enactment of section 505G, the process by which the Agency evaluates a request for an addition to or revision of an over-the-counter (OTC) monograph has changed. In particular, the addition of section 505G to the FD&C Act has changed the mechanism for establishing, amending, or withdrawing OTC monographs from a rulemaking process to an administrative order process.

Under section 505G(b) of the FD&C Act, FDA may, on its own initiative or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs is determined to be not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)) and generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). Under section 505G(b)(5) of the FD&C Act, a requestor seeking that the Secretary issue such an administrative order "shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary." As described in section 744L(7) of the FD&C Act (21 U.S.C. 379j-71(7)), such a request is termed an *OTC monograph order request* (OMOR). A

[1] Public Law No. 116-136, 134 Stat. 281 (March 27, 2020).

"requestor" is broadly defined in section 505G(q)(3) as "any person or group of persons marketing, manufacturing, processing, or developing a drug."

Because you are a *requestor*, as defined in section 505G(q)(3) of the FD&C Act and your Petition requests a type of relief that could be sought under an OMOR (see 505G(b)(5) of the FD&C Act), the citizen petition process is no longer the appropriate procedure for addressing your request, and your Petition is denied. Please note that information about the OMOR process is available on FDA's website[2] should you pursue that process for your request.[3]

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2023.05.17 14:32:30 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[2] See *OTC Drug Review Process | OTC Drug Monographs*, available at https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs; see also *Over-the-Counter (OTC) Drug Review | OTC Monograph Reform in the CARES Act*, available at https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#omor.

[3] If you are considering submitting an OMOR, we encourage you to request a Type Y pre-OMOR meeting prior to submitting the OMOR to discuss the OMOR process, the overall data recommended to support an OMOR submission, and the appropriateness of the OMOR process for your OTC drug development program. See FDA Guidance for Industry *Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs*, available at https://www fda.gov/media/155864/download. We note that treatment of migraine is not currently a permitted indication under any existing OTC drug monograph. See, e.g., M0013 Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use | FDA. At a pre-OMOR meeting, we could discuss recommendations for data on the indication, dosages, and other conditions for the drug you propose (i.e., a combination drug with the active ingredients acetaminophen, caffeine, and meclizine) to support an OMOR submission.