



February 25, 2022

Johnathan Smith, et. al.

(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your submission to the Commissioner of Food and Drug requesting that manufacturers of OTC products associating the terms “sinus” and “headache” (for example, but not limited to: Tylenol Sinus Plus Headache Day (NDC 50580-598-02), CVS Health Maximum Strength Sever Allergy & Sinus Headache Acetaminophen Tablets (NDC 59779-543-09), revise product names and box labelling to remove the direct linkage of these specific terms (e.g., “Sinus + Headache,” “Sinus plus headache,” and “Sinus headache”). Revision of “headache” to “pain” or “pressure” would be more acceptable was received and processed under CFR 10.30 by this office on 02/24/2022.

It was assigned docket number FDA-2022-P-0215. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency’s decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)