



Joe DiNardo
Personal Care Products Toxicologist

(b) (6)

February 23, 2023

Re: Docket No. FDA-2022-P-2077

Dear Mr. DiNardo:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 31, 2022. Your petition requests that the Agency “reclassify all Category III Sunscreen Actives (insufficient data available to permit final classification) from the Over-the-Counter (OTC) sunscreen drug monograph to Category II (Not GRASE) ‘OR’ incorporate appropriate warning statements....”

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett
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Digitally signed by Carol
Bennett -S
Date: 2023.02.23 10:13:59
-05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research