



August 31, 2022

Joe DiNardo

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Sent via email to: (b) (6)

Dear Petitioner:

Your submission requesting that the Commissioner to enforce the reclassification of Category III Sunscreen activities (insufficient data available to permit final classification) from the-over-the-counter (OTC) sunscreen monograph to Category II (Not Generally Recognized as safe & effective for human use) "OR" incorporate appropriate warning statements allowing consumers to understand the health risks associated with their use was received and processed under CFR 10.30 by this office on 08/31/2022.

It was assigned docket number FDA-2022-P-2077. 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,

Karen Malvin  
Acting Director  
Dockets Management Staff  
FDA/Office of Operations (OO)