



April 1, 2022

Alan G. Minsk
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Sent via email to: alan.minsk@agg.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug establish new science-base limits to control for 2-methyl-3-phenylaziridine in amphetamine salts APIs, because we believe that up to 0.099 percent contamination is too high a level for this aziridine impurity, and recommend that it be controlled to less than 0.01 percent was received and processed under CFR 10.30 by this office on 03/31/2022.

It was assigned docket number FDA-2022-P-0509. 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)

CC: Kadeja Watts (kadeja.watts@agg.com)