



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 7, 2019

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Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration and the Drug Enforcement Administration requesting to initiate the proceedings for rescheduling 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, its optical and geometric isomers, and salts of these isomers (including tramadol) from schedule IV to schedule II of the CSA was received by this office on 11/06/2019.

It was assigned docket number FDA-2019-P-5268. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)