



February 28, 2022

Timothy R. Cote
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Cambridge, MA 02142

Sent via email to: haris@onlyorphanscote.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug immediately and completely freeze all administrative actions on any regulatory requests from pharmaceutical and medical device companies headquartered in Russia or with majority Russian ownership was received and processed under CFR 10.30 by this office on 02/25/2022.

It was assigned docket number FDA-2022-P-0237. 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)