

January 23, 2024

Andrej Gasperlin DDReg Pharma, Inc. 1201 North Market Street, Suite 111 Wilmington, DE 19801

Sent via email to: usagent@ddregpharma.com

Dear Petitioner:

Your petition dated 01/17/2024 was received and processed under CFR 10.30 by this office on 01/19/2024 and it was assigned docket number FDA-2024-P-0427.

Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of this suitability 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

Karen Malvin Acting Director

Dockets Management Staff

FDA/Office of Operations (OO)