



**Suitability Petition
Completeness Assessment Correspondence**

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

Sent via email to: usagent@ddregpharma.com

Docket No. FDA-2024-P-0427

Dear Andrej Gasperlin:

This is in reference to your petition received on January 19, 2024, by the U.S. Food and Drug Administration (FDA or Agency) and your amendment dated February 15, 2024, requesting permission, in accordance with 21 C.F.R. §314.93(b), to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Progesterone Pessary, 400 mg. The petition was examined for initial completeness (i.e. Completeness Assessment) under CFR 10.30 and the Agency has made a threshold determination that the petition is complete.

This petition is subject to the provisions of the Generic Drugs User Fee Amendments of 2022 (GDUFA III) whereby any suitability petitions submitted in FY 2024-2027 will receive a goal date of 6 months after the completeness assessment. The GDUFA goal date for review of this petition is September 7, 2024.

If you have any questions, contact ANDAFiling@fda.hhs.gov.

A copy of this letter will be placed on public display in the Dockets Management



Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

{See appended electronic signature page}

Diana Guon, Pharm.D., BCPS
Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research



Diana
Guon

Digitally signed by Diana Guon

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