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 response 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 to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Progesterone Pessary, 400 mg. The listed drug product to which you refer in your petition is Crinone (Progesterone Gel), 8% approved under NDA 020701 and held by Allergan Sales LLC.

Your request involves a change in dosage form and strength from that of the listed drug product (i.e., from gel to pessary and from 8% (90 mg) to 400 mg). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act. However, for the reasons explained below, the Agency denies your request.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, that any of the proposed changes from the listed drug would require investigations to be conducted to show the safety and effectiveness of the proposed drug product or jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(i) and (iv).

The Agency has determined that your proposed changes in dosage form and strength raise questions of safety and effectiveness. There are no FDA approved drug products for a pessary dosage form. Investigations would need to be conducted to show the safety and effectiveness of this novel dosage form. Additionally, the proposed change in strength (400 mg) is more than four times the strength (8% (90 mg)) of the RLD, and investigations are required to show the safety and effectiveness of the proposed strength. The proposed changes may also jeopardize the safe or effective use of the product so as to necessitate

significant labeling changes to address the newly introduced safety or effectiveness problem.

Furthermore, according to your proposed drug product labeling, your request involves a change in indication and dosing regimen from that of the listed drug product. These are not types of changes for which the Agency will accept a petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and the implementing regulations at 21 CFR 314.93, which only allow for differences in route of administration, dosage form, or strength from that of a listed drug, or for one active ingredient to be substituted for one of the active ingredients in a listed combination drug. Thus, these changes cannot be approved in a petition under section 505(j)(2)(C).

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective, unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. See section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)]."). Because you are seeking a change in dosage form, this proposed product triggers PREA.

This petition is being denied because the proposed changes in dosage form and strength require investigations to be conducted to show the safety and effectiveness of the proposed drug product, and the proposed changes may jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem, and the changes in indication and dosing regimen are not one of the aforementioned changes authorized in section 505(j)(2)(C) of the Act and 21 CFR 314.93. Therefore, because your petition does not meet the applicable requirements under section 505(j)(2)(C) of the Act and 21 CFR 314.93, it is not necessary to address the question of whether pediatric studies are necessary under PREA. Please contact the Division of Urology, Obstetrics, and Gynecology at (301) 796 - 2130 if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial

following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Iilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

William
Chong

Digitally signed by William Chong
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