17 January 2024

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned, on behalf of a prospective ANDA applicant, submits this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 314.93 and 21 C.F.R. §§ 10.20 and 10.30, to request that the Commissioner of the U.S. Food and Drug Administration to make a determination of the RLD for an ANDA of a Progesterone based pessary formulation.

A. Action Requested

The petitioner requests the Commissioner of the U.S. Food and Drug Administration to make a determination of the RLD for an ANDA of a Progesterone based pessary formulation.

B. Statement of Grounds

FDC Act § 505(j)(2)(A)(iii) provides for the submission of an ANDA for a drug product that differs in strength from that of the listed drug provided FDA has first approved a petition permitting the submission of such an application.

The Orange book indicates different formulations of Progesterone are available with the same route of administration as that of the proposed generic product. A copy of the Orange book details of the available formulations is enclosed as ***Attachment-I***.

The proposed drug product also contains progesterone to be administered via vaginal route but in a different dosage form as well as strength of progesterone.

The petitioner's proposed drug product in a new form does not pose questions of safety or efficacy as the proposed indication remains same as that of the approved formulations. The uses and route

of administration are the same as those of the RLD. The prescribing information is enclosed as ***Attachment-II***.

The proposed drug product will be shown to be bioequivalent to the reference product in accordance with FDA usual criteria.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act (FDC Act § 505B) by requiring certain applications for a drug submitted under FDC Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen.

Petitioner asserts that PREA is not applicable to the proposed progesterone pessary formulation because Progesterone formulations are generally indicated for supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency. Accordingly, PREA should not serve as an impediment to the Agency granting this petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Sincerely,

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