LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

SARA W. KOBLITZ
Direct Dial (202) 737-9623
Skoblitz@hpm.com

May 23, 2024

SUBMITTED VIA REGULATIONS.GOV

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

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned, on behalf of a client, 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 ("FDA") declare that the drug product Cetrorelix Acetate Injection 0.25 mg/mL pre-filled syringe is suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The Petitioner requests that FDA declare that Cetrorelix Acetate Injection 0.25 mg/mL pre-filled syringe is suitable for submission as an ANDA. As designated in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), the Reference Listed Drug ("RLD") upon which this petition is based is EMD Serono, Inc.'s CETROTIDE® (Cetrorelix Acetate) Powder, which is approved for prescription use under New Drug Application ("NDA") 021197 as a 0.25 mg base/vial powder for reconstitution. The Petitioner seeks to introduce a new dosage form, a ready-to-use solution provided in a pre-filled syringe, as shown in the table below.

Product Details	**CETROTIDE (Cetrorelix Acetate) Injection (NDA 021197)**	**Petitioner's Proposed Cetrorelix Acetate Injection**
Active Ingredient	Cetrorelix Acetate	Cetrorelix Acetate
Route of Administration	Subcutaneous	Subcutaneous
Dosage Form	Powder	Solution
Strength (per mL)	EQ 0.25 mg base/vial	0.25 mg/mL
Package Type	Single dose vial	Single dose Pre-filled Syringe

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 dosage from that of the listed drug provided FDA has first approved a petition permitting the submission of such an application.

CETROTIDE, approved under NDA 021197, contains 0.25 mg/base powder for reconstitution (EQ 0.25 mg base/vial) of Cetrorelix Acetate for subcutaneous injection, and is provided in a kit with a syringe. A copy of the current Orange Book entry for CETROTIDE, EQ 0.25 mg base/vial, is included in ***Attachment 1***. The proposed drug product also contains Cetrorelix Acetate in 0.25 mg strength, but in a solution provided in a pre-filled syringe. The petition is thus seeking a change in dosage form from powder for reconstitution packaged with a syringe to a solution packaged in a pre-filled syringe.

The proposed change in dosage form is consistent with the dosing recommendations of the RLD's approved labeling. *See* Prescribing Information, CETROTIDE (Cetrorelix acetate) powder, EQ 0.25 mg base/vial (NDA 021197), Dosage and Administration (Dec. 2023), included as ***Attachment 2***. The new dosage form would provide a ready-to-use pre-filled syringe that removes the need for practitioners to reconstitute the product with the included Water for Injection, Pre-filled Syringe prior to use. Accordingly, it has the potential to reduce medication errors, as well as ease use of the product. The proposed change in dosage form from that of the RLD does not raise questions of safety or efficacy for the proposed drug product, and the ANDA will include information to demonstrate that the change in dosage form does not have an effect on the bioavailability of the Cetrorelix Acetate. Therefore, FDA should conclude that clinical investigations are not necessary to demonstrate safety or effectiveness of the proposed drug product.

There are no proposed changes in labeling with the exception of the change in dosage form sought in this petition. The uses, indications, warnings, and directions for use will remain the same as that of the RLD. Draft labeling for the proposed drug product is included as ***Attachment 3***. Annotated comparative draft labeling is included as ***Attachment 4***. Therefore, the Petitioner requests that FDA find that a change in dosage

form from a lyophilized powder for reconstitution to a solution provided in a pre-filled syringe raises no questions of safety or effectiveness.

Finally, we respectfully request a waiver of the applicable requirements pursuant to the Pediatric Research Equity Act ("PREA"). PREA, enacted in December 2003, amended the FDC Act 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. *See* FDC Act § 505B(a)(1)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. *See id.*

As a change in dosage form, PREA is applicable here. Nevertheless, Petitioner requests a waiver. FDA will waive PREA requirements when studies in pediatric patients are impossible or highly impracticable; there is evidence strongly suggesting that the drug would be ineffective or unsafe in all pediatric age groups; or when the drug (1) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and (2) is not likely to be used in a substantial number of pediatric patients. FDA, Guidance for Industry: Pediatric Drug Development: Regulatory Considerations — Complying With the Pediatric Research Equity Act and Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals for Children Act Guidance for Industry, at 12 (May 2023) ("PREA Regulatory Guidance").

This product is not intended for pediatric patient populations. The RLD, CETROTIDE, is indicated "to prevent premature ovulation during controlled ovarian stimulation" and is used exclusively in hormone treatments for fertilization. It provides no therapeutic benefit to pediatric patient groups and is not likely to be used in pediatric patients. Indeed, it is likely that this is the reason why the RLD sponsor received a pediatric waiver for the then-effective pediatric research requirements during its development in 2000. *See* Administrative Review at 11 ("Pediatrics Page"), NDA 021197 (Aug. 2000). Because the proposed generic product would be indicated for the same usage—as a fertility treatment in women of child-bearing age—its use would not be appropriate in pediatric patients. Consequently, a waiver is appropriate here.

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.

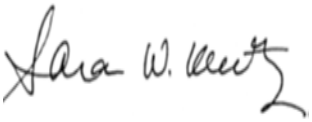
D. Economic Impact

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 which are unfavorable to the Petition.

Sincerely,



Sara W. Koblitz

SWK/rh
Attachments