DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 10, 2022

Hari Nagaradona, PhD
Vice President, US Regulatory Affairs
Ferring Pharmaceuticals, Inc.
100 Interpace Parkway
Parsippany, NJ 07054

Sent via email to: Hari.Nagaradona@ferring.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following three actions described below:

1) Require ANDAs that reference Firmagon, and 505(b)(2) applications that rely on bioequivalence data or comparative bioavailability data, to conduct an appropriate in vivo study capable of demonstrating that a proposed drug product causes degarelix acetate to release into systemic circulation at the same rate and to the same extent as the RLD over the course of the dosing interval;
2) Require ANDA and 505(b)(2) sponsors to conduct partial Area Under the Curve (pAUC) analysis as part of the in vivo bioequivalence study to ensure the generic is bioequivalent to the RLD over the required dosing interval; and
3) Re-issue the Draft Guidance based on the actions taken in response to this petition.

This petition was received by this office on 02/10/2022 and it was assigned docket number FDA-2022-P-0160. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.15 15:40:50 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)