U.S. FOOD & DRUG ADMINISTRATION

Hari Nagaradona, Ph.D.
Vice President, U.S. Regulatory Affairs
Ferring Pharmaceuticals, Inc.
100 Interpace Parkway
Parsippany, NJ 07054

August 9, 2022

Re: Docket No. FDA-2022-P-0160

Dear Dr. Nagaradona:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on February 10, 2022. Your petition requests that the Agency take the following actions:

1. Require abbreviated new drug applications (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 reference listed drug over the course of the dosing interval;

2. Require ANDA and 505(b)(2) applicants to conduct partial Area Under the Curve analysis as part of the in vivo bioequivalence study to ensure the generic is bioequivalent to the reference listed drug over the required dosing interval; and

3. Re-issue the Agency's March 2021 draft product-specific guidance entitled Draft Guidance on Degarelix Acetate based on the actions taken in response to the Petition.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2022.08.09 12:21:42 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
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