December 7, 2022

David M. Fox
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Sent via email to: david.fox@hoganlovells.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug reconsider the November 4, 2022 decision denying Ferring's Citizen Petition requesting the FDA require in vivo studies for proposed generic versions of Firmagon® (degarelix acetate) and update accordingly its product-specific bioequivalence guidance for degarelix acetate by stating that the FDA failed to adequately consider several critical issues, unnecessarily exposing patients to serious risk:

(1) First, FDA failed to address data and a statistical analysis presented by Ferring showing that in vitro dissolution tests are not adequately sensitive to detect changes in in vivo bioavailability of the reference product, Firmagon® (degarelix acetate). The agency's response entirely ignores the potential for reaching an erroneous conclusion when relying on in vitro testing in this instance, as shown by Ferring's data and analysis.
(2) Second, FDA does not address scientific literature presented by Ferring that shows the difficulty in characterizing the in vitro variables affecting Firmagon's in vivo bioavailability. Specifically, a study cited by Ferring, and published with support from staff within FDA's Center for Drug Evaluation and Research, states that a valid method for such characterization is not available. The agency responded only by saying it does not agree. It does not address the underlying data or rationale.
(3) Third, FDA failed to adequately consider the serious risk of treatment failure for patients with advanced prostate cancer as a result of approving a generic version of Firmagon base solely on an untested in vitro model.
(4) Fourth, the agency's bioequivalence recommendations for degarelix are in conflict with its binding regulation and its prior policies for systemically-absorbed and extended-release drug products.

The petition was received and processed under CFR 10.30 by this office on 12/05/2022. It was assigned docket number FDA-2022-P-0160. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, 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: 2022.12.12 19:34:19 -05'00'

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

cc: Jason.conaty@hoganlovells.com