DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 23, 2013

Charles B. Klein
WINSTON & STRAWN LLP
Counsel for Petitioner
Sun Pharmaceutical Industries, Ltd.
1700 K Street, NW
Washington, DC 20006

Dear Mr. Klein:

Your petition to the Food and Drug Administration on behalf of Sun Pharmaceutical Industries, Ltd., requesting the Agency to confirm that Ganirelix is not approved by the FDA for use as a female contraceptive; and the FDA-labeled indication for Ganirelix is not equivalent to a method of female contraception, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1292/CP1, and it was filed on 10/23/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)