DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

FEB 0 7 2014

Charles B. Klein
Winston & Strawn LLP
1700 K Street, NW
Washington, DC 20006

Re: Docket No. FDA-2013-P-1292

Dear Mr. Klein:

This letter responds to your citizen petition submitted to the Food and Drug Administration (FDA or the Agency) on behalf of Sun Pharmaceutical Industries, Ltd., and dated October 17, 2013 (Petition). Your petition requests that FDA confirm that (1) FDA has not approved Ganirelix Acetate Injection for use as a female contraceptive, and (2) the FDA-labeled indication for Ganirelix[1] is not equivalent to a method of female contraception.

FDA has carefully reviewed your petition. For the reasons described below, your petition is granted in part and denied in part.

I. DISCUSSION

Ganirelix Acetate Injection is the subject of new drug application (NDA) 021-057, which is held by Organon USA Inc. FDA approved Ganirelix on July 29, 1999, for the "inhibition of premature LH [luteinizing hormone] surges in women undergoing controlled ovarian hyperstimulation."[2]

You request that FDA confirm that FDA has not approved Ganirelix Acetate Injection for use as a female contraceptive (Petition at 1). You note that the FDA-approved labeling for Ganirelix "does not even mention use of the product as a contraceptive, much less designate contraception as an approved indication for the drug" (Petition at 3). We agree and grant this request. As stated above, FDA approved Ganirelix for the "inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation." FDA has not approved Ganirelix for use as a female contraceptive.

You also request that FDA confirm that the FDA-labeled indication for Ganirelix is not equivalent to a method of female contraception (Petition at 1). You state that the "labeled

[1] Throughout this response, we refer interchangeably to "Ganirelix Acetate Injection" and "Ganirelix."

[2] See FDA-approved labeling for Ganirelix Acetate Injection, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021057s007lbl.pdf.

indication for Ganirelix is not equivalent to, nor substantially the same as, a method of female contraception" (Petition at 4). We deny your request. It is not clear what the term "equivalent" means in the context of your request. As previously described, the FDA-approved indication for Ganirelix Acetate Injection is the "inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation." Ganirelix is not indicated for use as a female contraceptive.

II. CONCLUSION

For the reasons described above, your petition is granted in part and denied in part.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research