DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Kevin Barber, Ph.D., R.A.C., P.M.P.
Vice President, Regulatory Affairs
Watson Laboratories
577 Chipeta Way
Salt Lake City, UT 84108-1222

Re: Docket No. FDA-2013-P-0664

Dear Dr. Barber:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 4, 2013. Your petition requests that the Agency:

(1) Refuse to approve any abbreviated new drug application for a generic version of Crinone (progesterone gel), 4% and 8% (new drug application 020701) unless and until such sponsor demonstrates bioequivalence in both a study with pharmacokinetic endpoints and in a clinical endpoint bioequivalence study; and
(2) Issue draft guidance on progesterone gel identifying the bioequivalence studies under item number (1) and consistent with the Agency's Draft Guidance on Progesterone (generic Endometrin), recommended September 2012.

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

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research