DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 4, 2013

FILE COPY

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

Dear Dr. Baber:

Your petition to the Food and Drug Administration requesting to require certain bioequivalence criteria to approve an Abbreviated New Drug Application for generic CRINONE, and issue draft guidance on Progesterone Gel consistent with the Agency's Draft Guidance on Progesterone (generic ENDOMETRIN®) recommended in September 2012, was received by this office on 06/04/2013. It was assigned docket number FDA-2013-P-0664/CP1, and it was filed on 06/04/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-0664

ACK