DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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December 2, 2013

William S. Craig, Ph.D.
Founder and Principal Consultant
Craig Pharma Solutions, LLC
P.O. Box 910361
San Diego, CA 92121

Dear Mr. Craig:

Your petition to the Food and Drug Administration requesting the Agency to refrain from approving any ANDA or 505(b)(2) application for acetaminophen solution injection product that does not contain the same inactive ingredients as Ofirmev (acetaminophen injection) unless the ANDA or 505(b)(2) application includes evidence from nonclinical studies and adequate and well controlled clinical trials demonstrating that any change in formulation does not affect the safety or effectiveness of the proposed new product, was received by this office on 11/4/2013. It was assigned docket number FDA-2013-P-1508/CP1, and it was filed on 12/2/2013. 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)