DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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August 12, 2013

David B. Clissold
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Dear Mr. Clissold:

Your petition to the Food and Drug Administration requesting that FDA refuse to file any 505(b)(2) new drug application ("NDA") for a buprenorphine/naloxone drug product consisting of a polymer film for application to the oral mucosal membranes unless such NDA references the NDA for the SUBOXONE® sublingual film product, and to reaffirm that any such 505(b)(2) NDA will be subject to the impurity limits for naloxone established by FDA in response to a 2009 citizen petition (Docket No. FDA-2009-P-0325), was received by this office on 8/12/2013. It was assigned docket number FDA-2013-P-0995/CP1, and it was filed on 8/12/2013. 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)