



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 31, 2012

Frederik Defesche
President
Custo Pharm, Inc.
2325 Camino Vida Roble
Suite A
Carlsbad, CA 92011

FILE COPY

Dear Mr. Defesche:

Your petition to the Food and Drug Administration requesting to designate generic Clotrimazole Troche/Lozenge, ANDA 076387 as second reference listed drug for the purpose of submitting an abbreviated new drug application, was received by this office on 12/31/2012. It was assigned docket number FDA-2013-P-0028/CP1, and it was filed on 12/31/2012. 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-0028

ACK