DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 6, 2013

Jerry Treppel
CEO
Elite Laboratories, Inc
165 Ludlow Avenue
Northvale, NJ 07647

Dear Mr. Treppel:

Your petition to the Food and Drug Administration requesting to make a determination that approved and marketed product for ANDA 078648 (dexbrompheniramine maleate, 6mg/ pseudoephedrine sulfate 120 mg, extended release, is suitable to use as a Reference Listed Drug (N013483 Drixoral, (dexbrompheniramine maleate 6mg/ pseudoephedrine sulfate, 120 mg, extended release) and that this currently approved and marketed ANDA product is suitable to use as RLD for a product containing an equivalent amount of an active ingredient which is comprised of a different salt, was received by this office on 06/06/2013. It was assigned docket number FDA-2013-P-0694/CP1, and it was filed on 06/06/2013. 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)