



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 13, 2013

Emmalyn Caoili
Regulatory Affairs Manager
BioKey, Inc.
44370 Old Warm Springs Blvd.
Fremont, CA 94538

Dear Ms. Caoili:

Your petition to the Food and Drug Administration on behalf of Trigen Laboratories, requesting to amend the "Orange Book" to assign a second reference listed drug (RLD) product for Bisoprolol Fumarate tablets, was received by this office on 3/13/2013. It was assigned docket number FDA-2013-P-0299/CP1, and it was filed on 03/13/2013. 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,

A handwritten signature in cursive script, reading "Gloria Ortega", is positioned above the printed name.

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