DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

SEP 0 9 2013

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

Re: Docket No. FDA-2013-P-0299

Dear Ms. Caoili:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 13, 2013, and submitted on behalf of Trigen Laboratories. Your petition requests that the Food and Drug Administration (FDA or the Agency) amend FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) to assign a second reference listed drug (RLD) for bisoprolol fumarate tablets. Specifically, you request that FDA designate Sandoz Inc.'s abbreviated new drug application (ANDA) 075643 for bisoprolol fumarate tablets and/or Mylan Pharmaceutical Inc.'s ANDA 075831 for bisoprolol fumarate tablets as RLD(s).

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research