BIOKEY, INC.

2013 MAR 13 P 12:30

March 4, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

This petition is hereby submitted pursuant to 21 CFR 10.30 and in accordance with 21 CFR 314.94 to request the Commissioner of the Food and Drug Administration to amend the "Approved Drug Products with Therapeutic Equivalence Evaluation" list (the "Orange Book") 32nd Edition as outlined below.

A. Action Requested

The petitioner, Trigen Laboratories, through the undersigned authorized agent, requests FDA to amend the "Orange Book" to assign a second reference listed drug (RLD) product for Bisoprolol Fumarate Tablets.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as Abbreviated New Drug Applications. That list referred to as the "Orange Book," contains all the FDA-approved drug products. This list is accessible via http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

The Orange Book website designates TEVA Womens' ZEBETA® (Bisoprolol Fumarate) Tablets as the Reference Listed Drug for 10 mg.

44370 Old Warm Springs Blvd., Fremont, CA 94538 Tel: (510)668-0881, Fax: (510)252-0188

FDA-2013-P-0299

2013-1826 CP

Over a period of almost 24 months, the petitioner and BioKey Inc., drug product developer, attempted to procure TEVA Womens' ZEBETA® Tablets 10 mg to support its ANDA submission without success. The wholesale distributors contacted have repeatedly indicated that ZEBETA® Tablets 5 mg and 10 mg are not available for commercial distribution from TEVA Womens. Thus, unavailability of the RLD has delayed the submission of an ANDA by the petitioner.

In the "Orange Book" website there are six manufacturers (see attached printed pages) listed for Bisoprolol Fumarate Tablets including Teva Womens, the NDA holder of the RLD. All six manufacturers (Aurobindo Pharma, Mylan, Sandoz, Teva Pharms, Teva Womens, and Unichem Pharms) have both 5 mg and 10 mg strengths approved.

The "Orange Book" designates an "AB" rating for the RLD and all approved generic drug products. AB-rated drugs are drugs that meet the necessary bioequivalence standards established by the Food and Drug Administration (FDA). Hence, bioequivalence studies for the proposed bisoprolol fumarate generic application will be conducted per the FDA's Bioequivalence Guidance on Bisoprolol Fumarate finalized on May 2008. The petitioner requests the Agency to designate the products of Sandoz and/or Mylan as Reference Listed Drug/s as they have both the 5 mg and 10 mg strengths and that they are always in stock and readily available in the market.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Certification

I hereby certify, to the best of my knowledge and belief, that this petition includes all information and views on which the petition relies, and that there are no known data or information unfavorable to the petition.

Respectfully,

Emmalyn Caoili, RAC
Regulatory Affairs Manager
BioKey, Inc. (Designated Agent, Trigen Laboratories)

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Enclosures:
1. Printed pages on Bisoprolol Fumarate from "Orange Book" website
2. Trigen Authorization Letter

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

FDA Home

Active Ingredient Search Results from "OB_Rx" table for query on "bisoprolol fumarate."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
A077910	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	10MG	BISOPROLOL FUMARATE	AUROBINDO PHARMA
A077910	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	5MG	BISOPROLOL FUMARATE	AUROBINDO PHARMA
A075831	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	10MG	BISOPROLOL FUMARATE	MYLAN
A075831	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	5MG	BISOPROLOL FUMARATE	MYLAN
A075643	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	10MG	BISOPROLOL FUMARATE	SANDOZ
A075643	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	5MG	BISOPROLOL FUMARATE	SANDOZ
A075644	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	10MG	BISOPROLOL FUMARATE	TEVA PHARMS
A075644	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	5MG	BISOPROLOL FUMARATE	TEVA PHARMS
N019982	AB	Yes	BISOPROLOL FUMARATE	TABLET; ORAL	10MG	ZEBETA	TEVA WOMENS
N019982	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	5MG	ZEBETA	TEVA WOMENS
A078635	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	10MG	BISOPROLOL FUMARATE	UNICHEM PHARMS (USA)
A078635	AB	No	BISOPROLOL FUMARATE	TABLET; ORAL	5MG	BISOPROLOL FUMARATE	UNICHEM PHARMS (USA)
A075768	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	10MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	MYLAN
A075768	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	2.5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	MYLAN

A075768	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	MYLAN
A075579	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	10MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	SANDOZ
A075579	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	2.5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	SANDOZ
A075579	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	SANDOZ
N020186	AB	Yes	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	10MG;6.25MG	ZIAC	TEVA WOMENS
N020186	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	2.5MG;6.25MG	ZIAC	TEVA WOMENS
N020186	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	5MG;6.25MG	ZIAC	TEVA WOMENS
A079106	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	10MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	UNICHEM
A079106	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	2.5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	UNICHEM
A079106	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	UNICHEM
A075469	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	10MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	WATSON LABS
A075469	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	2.5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	WATSON LABS
A075469	AB	No	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE	TABLET; ORAL	5MG;6.25MG	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE	WATSON LABS

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through January, 2013
Patent and Generic Drug Product Data Last Updated: February 20, 2013

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

TRIGEN
LABORATORIES

To Whom It May Concern:

Trigen authorizes Emmalyn Caoili, RAC Regulatory Affairs at BioKey, Inc. to represent Trigen in the Citizen's Petition regarding an ANDA submission for Teva Women's drug product Zebeta© (Bisoprolol Fumarate) 5mg, and 10mg tablets.

Dave Purdy

President
Trigen Laboratories, Inc.

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