DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-515/S-023
NDA 21-515/S-024

Biovail Technologies, Ltd.
700 Route 202/206 North
Bridgewater, NJ 08807

Attention: Robert W. Ashworth, PhD
Vice President, Regulatory Affairs

Dear Dr. Ashworth:

Please refer to your supplemental new drug applications dated December 11, 2008 and March 19, 2009, received December 11, 2008 and March 19, 2009, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for WELLBUTRIN XL (bupropion hydrochloride extended-release) Tablets.

Reference is also made to our letter dated February 19, 2009, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for bupropion-containing drug products. This information pertains to the risk of suicidality-related events associated with the use of these products.

Supplement S-023, submitted as a "Changes Being Effected" supplemental new drug application, provides the following changes to the package insert label:

1. **CLINICAL PHARMACOLOGY: Renal** and **PRECAUTIONS: Renal Impairment**- Addition of a description of a study comparing the use of bupropion in normal subjects and patients with moderate-to-severe renal impairment.

2. **PRECAUTIONS: Pregnancy**- Deletion of the Bupropion Pregnancy Registry enrollment telephone number since the registry was closed as of November 1, 2007.

3. **OVERDOSAGE**- Addition of QRS prolongation as a reported adverse reaction of overdoses of bupropion under "Human Overdose Experience". Deletion of the statement recommending gastric lavage under "Overdosage Management".

Supplement S-024 provides for revisions to the package insert and Medication Guide consistent with our letter dated February 19, 2009.

We also refer to the email correspondence between FDA and Biovail Technologies dated May 28, June 5, 11, 15 and 16, 2009, in which agreement was reached on these safety labeling changes.

We have completed our review of these supplemental applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved supplements NDA 21-515/S-023 and S-024."**

Marketing the product with final printed labeling that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact Renmeet Grewal, Regulatory Project Manager, at (301)796-1080.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Cc: SmithKline Beecham Corporation
d/b/a GlaxoSmithKline
5 Moore Drive
Research Triangle Park, NC 27709

Attention: Mary E. Martinson
Senior Director, Psychiatry
U.S. Regulatory Affairs

Enclosure: Package Insert labeling/Medication Guide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mitchell Mathis
7/1/2009 10:45:49 AM
For Dr. Laughren