DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-763

Biovail Technologies, Ltd.
Attention: Jacqueline Little, M.Sc.
Director, Regulatory Liaison
700 Route 202-206 North
Bridgewater, NJ 08007

Dear Ms. Little:

Please refer to your new drug application (NDA) dated April 14, 2004, received April 14, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Citalopram Hydrobromide Orally Disintegrating (ODT) 10 mg, 20 mg, 30 mg, and 40 mg Tablets.

We acknowledge receipt of your submissions dated May 4, May 9, June 23, November 4, November 15, December 7, and December 12, 2005.

The June 23, 2005 submission, received June 24, 2005, constituted a complete response to our February 14, 2005 action letter.

This new drug application provides for the use of Citalopram Hydrobromide orally disintegrating tablets to treat major depressive disorder.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and Medication Guide). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved NDA 21-763**." Approval of this submission by FDA is not required before the labeling is used.

Tradename

Please note that we are approving this application without a tradename. If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. Therefore, if you wish to market this drug with a tradename, you will be required to submit a "Prior Approval" labeling supplement to your NDA.

Pediatric Studies
All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

Medication Guide
We have determined that the major depressive disorder therapeutic class of drugs poses a serious and significant public health concern relating to pediatric suicidality. This concern requires the distribution of a Medication Guide under 21 CFR 208 in order to prevent serious adverse effects, inform patients of information concerning risks that could affect their decision to use or continue to use the drug, and/or assure effective use of the drug. Since citalopram orally disintegrating tablets belongs in this therapeutic class, it will need to be accompanied by a Medication Guide.

We note your agreement to the enclosed Medication Guide. Under 21 CFR 208, you are responsible for ensuring that the Medication Guide is available for every patient who is dispensed citalopram orally disintegrating tablets. Optimally, the Medication Guide would be attached to unit-of-use packaging to ensure that every patient receives the Medication Guide.

Therefore, you will need to format the proposed Medication Guide in a manner that will assure its appropriate distribution to patients. In addition, when you eventually submit a proposed trade name, the submission should also contain your proposed container and/or carton labels for citalopram orally disintegrating tablets that include a prominent and conspicuous instruction to provide the Medication Guide to each patient dispensed the drug. The labels must that state how the Medication Guide is provided (e.g., affixed on the container, provided with the product, etc.).

Expiration
We grant an 18-month expiry for all three dosage strengths of Citalopram ODT (10 mg, 20 mg and 40 mg) based on the available stability data.

Dissolution Methodology
We note your agreement to adopt the following dissolution method and specification for all strengths (10 mg, 20 mg, 30 mg, and 40 mg) of Citalopram ODT tablets:

Method: USP Apparatus 2 (b)(4)
Speed: (b)(4)
Medium: (b)(4) ml of pH (b)(4) buffer for 40 mg ODT;
(b)(4) ml of pH (b)(4) buffer for 10 mg and 20 mg ODT
Specification: Q = (b)(4) in 30 minutes

Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications

Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, call Renmeet Gujral, Regulatory Project Manager at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Thomas Laughren
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