CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022497Orig1s000

Trade Name: Forfivo XL

Generic Name: Bupropion Hydrochloride Extended Release Tablets

Sponsor: IntelGenx Corp.

Approval Date: 11/10/2011

Indications: For the Treatment of Major Depressive Disorder (MDD).

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022497

NDA APPROVAL

IntelGenx Corp
Attention: Bethany Hills, JD, MPH, Esq.
Hodgson Russ LLP
The Guaranty Building
140 Pearl Street, Suite 100
Buffalo, NY 14202-4040

Dear Ms. Hills:

Please refer to your New Drug Application (NDA) dated March 31, 2009, received April 6, 2009, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FORFIVO XL (bupropion hydrochloride 450 mg extended-release) tablets.

We acknowledge receipt of your amendments dated:

April 2, 2010	August 2, 2010	June 29, 2011	November 4, 2011
April 6, 2010	October 14, 2010	September 8, 2011 [2]	November 9, 2011
May 10, 2010 [3]	May 4, 2011	September 9, 2011	
June 1, 2010	June 8, 2011	September 20, 2011	

The May 4, 2011, submission which was received May 13, 2011, constituted a complete response to our February 3, 2010, action letter.

This new drug application provides for the use of FORFIVO XL (bupropion hydrochloride 450 mg extended-release) tablets for Major Depressive Disorder.

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

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

APPROVED DISSOLUTION METHOD AND SPECIFIATION

The approved dissolution acceptance criteria are as follows:

Dissolution Acceptance Criteria			
Acid Stage		Buffer Stage	
Time (hrs)	% Dissolved	Time (hrs)	% Dissolved
2	NMT (b) (4)	4	(b) (4)
		8	
		16	NLT (b) (4)

EXPIRY DATE

An expiration date of 24 months has been granted for this product.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the Medication guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 022497**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application for several reasons. First, a 450 mg dose would likely result in an unnecessarily high and possible unsafe exposure in most pediatric patients, given the steep dose response relationship for seizure. Therefore, this drug product would likely be unsafe in most pediatric patients. Second, although there may be rare pediatric patients who might benefit from this dose, it would be impossible or highly impractical to conduct a study in such a limited and difficult to recruit population. Finally, given the likelihood that exceedingly few pediatric patients would likely benefit from this product, it cannot be considered to represent a meaningful therapeutic benefit over existing therapies for pediatric patients. Thus, there would be no compelling public health reason to even attempt to conduct such a study.

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, contact CDR Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at (301)796-4158 or email: Kofi.Ansah@fda.hhs.gov.

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

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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

/s/

THOMAS P LAUGHREN
11/10/2011