



NDA 202133/S-004/S-005

## SUPPLEMENT APPROVAL

Edgemont Pharmaceuticals, LLC  
Attention: Cheri L. Cox  
Principal Scientist, Clinical Research  
Cardinal Health Regulatory Sciences  
7400 West 110th Street, Suite 300  
Overland Park, Ks 66210

Dear Ms. Cox:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 25, 2016 (S-004), and October 12, 2016 (S-005), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fluoxetine 60 mg tablets.

We also refer to our letter dated September 21, 2016, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for all selective serotonin reuptake inhibitor (SSRI) and serotonin and norepinephrine reuptake inhibitor (SNRI) products. This information pertains to the addition of "amphetamine" to list of serotonergic drugs which can potentially increase risk for serotonin syndrome.

These supplemental new drug applications provide for the following revisions to product labeling:

### **S-004**

- Revise the full prescribing information and Medication Guide (FPI/MG) for consistency with the FPI/MG for the referenced listed drug, Prozac.

### **S-005**

- Revisions to the labeling for fluoxetine consistent with our September 21, 2016 letter.

## **APPROVAL & LABELING**

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

## **WAIVER OF HIGHLIGHTS SECTION**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

## **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, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **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 Hiren Patel, Senior Regulatory Project Manager, at (301) 796- 2087 or at [Hiren.Patel@fda.hhs.gov](mailto:Hiren.Patel@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, MD  
Division Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MITCHELL V Mathis  
01/04/2017