DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022033/S-003/S-006/S-007

SUPPLEMENT APPROVAL

Jazz Pharmaceuticals
Attention: Jennifer Ekelund
Executive Director, Regulatory Affairs
3180 Porter Drive
Palo Alto, CA 94304

Dear Ms. Ekelund:

Please refer to your Supplemental New Drug Applications (sNDAs) dated June 26, 2009 (S-003) and April 14, 2010 (S-006 and S-007), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Luvox CR (fluvoxamine maleate) extended-release Capsules.

•NDA 022033/S-003/S-007: We acknowledge receipt of your July 2, 2010 correspondence and your February 4, 2011 and March 3, 2011 amended labeling. We also refer to our June 21, 2010 Complete Response letter and your September 20, 2010 response.

•NDA 022033/S-006: We reference our March 15, 2010 request for a comprehensive Medication Guide (MG). We also reference our September 24, 2010 Complete Response letter and your October 14, 2010 response as well as your February 4, 2011 and March 3, 2011 amended labeling.

These "Prior-Approval" supplemental new drug applications propose the following revisions to product labeling:

S-003: Conversion of the labeling to adhere to the Physician Labeling Rule
S-006: Addition of a comprehensive Medication Guide (MG)
S-007: Removal of the adult social anxiety disorder (SAD) indication

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter. The agreed-upon labeling is attached.

We would like to remind you of the agreement regarding S-007 referenced in our March 4, 2010 preliminary comments in which we stated that we would not deny your request to voluntarily withdraw the SAD indication. However, with removal of the SAD indication from the approved Luvox CR labeling, you are not permitted to promote the drug for this indication. As described in a letter issued separately today, you are released from the PREA and maintenance study requirements associated with the SAD indication. If you decide to seek approval for the SAD indication at some later date, you will need to submit a NDA supplement. The supplement will

trigger the requirement for a pediatric assessment in the SAD indication under PREA and you will need to recommit to carry out a maintenance study in SAD.

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 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 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).

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 questions, call Kimberly Updegraff, M.S., Senior Regulatory Project Manager, at (301)796-2201.

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

ENCLOSURE:
Content of 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
05/09/2011