DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-519 / S-001
NDA 22-033 / S-002

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

Dear Ms. Ekelund:

We acknowledge receipt of your supplemental new drug applications dated February 13, 2009, received February 17, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Luvox (fluvoxamine maleate) Tablets and Luvox CR (fluvoxamine maleate) Extended-release Capsules.

Reference is also made to the FDA letter dated December 4, 2008, notifying you, under section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Luvox and Luvox CR. This information pertains to the risk of neuroleptic malignant syndrome associated with use of selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs), including the Luvox products.

We additionally refer to our extension letter of January 30, 2009, and our email communications of January 23, 26, 30, and February 10, 12, and 13, 2009.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed submitted labeling text.

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 in content to the enclosed labeling. 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 NDAs 21-519 / S-001 and 22-033 / S-002."**

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

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

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call Renmeet Grewal, Pharm. D., Senior 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

Enclosures - 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 Laughren
2/24/2009 03:15:01 PM