CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-235

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY
Response to AE Letter

NDA:	22-235
Submission Type	PLR Labeling
Submission Date(s):	January 30, 2008
Brand Name	Luvox ®
Generic Name	Fluvoxamine Maleate
Formulation; Strength(s)	25, 50, 100 mg Tablets
Sponsor	Jazz Pharmaceuticals Palo Alto, CA
Primary Reviewer	Carol Noory
Team Leader	Raman Baweja
OCP Division	Division of Clinical Pharmacology I
ORM division	Division of Psychiatry Products (DPP) HFD-130
Indication	Treatment of Obsessive Compulsive Disorder

INTRODUCTION

NDA 22-235 was submitted on June 21, 2007 and accepted for filing on August 28, 2007. This NDA was established to review the data from study S114.2.09, a maintenance study in adult patients with OCD, and provided a draft package insert in the new PLR labeling format. On December 3, 2007, the Division requested that the draft labeling be amended.

In Table 1, the draft label for NDA 22-235 submitted January30, 2008 is compared to the approved label for Luvox® tablets, NDA-21-519.

RECOMMENDATION

The Office of Clinical Pharmacology has reviewed the pertinent parts of the "Clinical Pharmacology", "Drug Interactions" and the "Dosage and Administration" Sections of the Labeling submitted by the firm. The labeling is acceptable as revised provided an agreement is reached between the sponsor and the Agency regarding minor corrections in the labeling. The following comments should be sent to the sponsor.

The Medical Officer should review the comments provided and finalize recommendations regarding those sections.

COMMENTS TO THE SPONSOR

Minor changes are recommended in the WARNINGS AND PRECAUTIONS section and the DRUG INTERACTIONS

1. [redacted] The sentence at the end of the paragraph should read:

   "Ramelteon should not be used in combination with fluvoxamine."

2. [redacted] Alcohol: The following sentence should be added:
   "As with other psychotropic medications, patients should be advised to avoid alcohol while taking LUVOX Tablets"

COMMENTS TO THE MEDICAL OFFICER

There are minor differences between the proposed draft label and the approved Luvox® IR tablet.

[redacted]

SIGNATURES

Reviewer: Carol Noory Date: _____

Team Leader: Raman Baweja Date: _____

cc list:
DFS: NDA 22-235

HFD-860: (NooryC, BawejaR, UppoorR, MehtaM)
HFD-120: (GrewalR, BenderW, LaughrenT, OliverT,)

20 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Clin Pharm/Bio- 2

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

/s/

Carol Noory
2/14/2008 01:29:51 PM
BIOPHARMACEUTICS

Raman Baweja
2/14/2008 02:20:55 PM
BIOPHARMACEUTICS