CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-473

OTHER REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	October 1, 2009
To:	Norman Stockbridge, M.D. Division Director
	Division of CardioRenal Products
Through:	Claudia Karwoski, PharmD, Director
	Division of Risk Management
	LaShawn Griffiths, MSHS-PH, BSN, RN, Acting Team Leader
	Division of Risk Management
From:	Steve L Morin, RN, BSN
	Patient Labeling Reviewer
	Division of Risk Management
Subject:	Memo to file re: Revatio I.V. PPI
Drug Name(s):	Revatio (sildenafil)
Application Type/Number:	NDA 22-473
Applicant/sponsor:	Pfizer Labs
OSE RCM #:	2009-445

The Division of CardioRenal Products (DCRP) requested that the Division of Risk Management review proposed patient labeling for New Drug Application (NDA) 22-473 submitted by Pfizer Labs for Revatio (sildenafil) I.V.

Based on discussion at the mid-cycle meeting on September 21, 2009 it was agreed that a Patient Package Insert (PPI) was not necessary for Revatio (sildenafil) I.V. because the drug would only be dispensed by a hospital pharmacy and is intended for inpatient use only. The current Patient Package Insert (PPI) for Revatio 20mg tablets was reviewed in May 2009. The Division of Risk Management will close out our consult request for Revatio (sildenafil) I.V.

Please let us know if you have any questions.

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/s/

STEVE L MORIN
10/01/2009

CLAUDIA B KARWOSKI
10/01/2009
concur

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	August 28, 2009
To:	Norman Stockbridge, MD, Director Division of Cardiovascular and Renal Products
Through:	Melina Griffis, RPh, Acting Team Leader Denise Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis
From:	Anne Crandall, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Label and Labeling Review
Drug Name(s):	Revatio (Sildenafil Citrate) Injection, 10 mg/12.5 mL (0.8 mg/ mL)
Application Type/Number:	NDA 22-473
Applicant/sponsor:	Pfizer
OSE RCM #:	2009-447

EXECUTIVE SUMMARY

This review is written in response to a March 11, 2009 request from the Division of Cardiovascular and Renal Products (DCRP) for an assessment of the labels and labeling for the product, Revatio (Sildenafil) Injection (NDA# 22-473), to identify areas that could lead to medication errors.

Revatio is currently available as a 20 mg tablet under NDA # 21-845 for the indication of pulmonary arterial hypertension (PAH). Sildenafil is also marketed as Viagra under NDA # 20-895 for the indication of erectile dysfunction and is available as a 25 mg, 50 mg and 100 mg tablet. Revatio Injection will be the first available phosphodiesterase type-5 (PDE5) intravenous solution and will be dosed at 12.5 mg three times daily in bolus intravenous doses.

Using Failure Mode and Effects Analysis,[1] the Division of Medication Error Prevention and Analysis (DMEPA) evaluated the container labels, carton labeling and insert labeling to identify vulnerabilities that could lead to medication errors.

Our findings indicate that the presentation of information in the labels and labeling introduces vulnerability to confusion that could lead to medication errors. We provide recommendations below that aim at reducing the risk of medication errors. We would be willing to meet with the Division for further discussion, if needed. Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Sean Bradley, project manager, at 301-796-1332.

1 MATERIALS REVIEWED

For this product the Applicant submitted labels and labeling as part of the December 16, 2008 new NDA submission for Revatio Injection. Subsequent to the submission, revised labels were submitted on August 3, 2009 to reflect discussion that occurred between the Applicant and the Agency. These labels were revised based on a change to the vial size from [redacted] to a 12.5 mL size. b(4)

2 RECOMMENDATIONS

We request the following recommendations be communicated to the Applicant prior to approval.

2.1 COMMENTS TO THE APPLICANT

A. General Comments (All Labels and Labeling)

1. The presentation of the dosage form in conjunction with the established name should be revised to read (Sildenafil Citrate) Injection in accordance with the recommendations made by the reviewing chemist. This change should be made to all product labels and labeling, including the package insert.

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[1] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

2. Revise the presentation of the strength of the vial to be expressed in terms of total drug content followed by the concentration, for example:

[redacted] b(4)

B. Container Label and Carton Labeling

1. Revise the statement "[redacted]" to read "Sterile Single-use Vial, Discard Unused Portion". b(4)

2. Revise the '[redacted]' statement to read "For Intravenous Use". Additionally, relocate the statement so that it is presented below the strength to ensure that there is no intervening matter between the proprietary name and strength. b(4)

1 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

✓ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

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/s/

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