CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022377Orig1s000

PHARMACOLOGY REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application Number: 22-377

Submission Number/code: 000/Original Submission

CDER Stamp Date: 17 July 2008

PDUFA Date: 17 May 2009

Product: Sumatriptan Succinate Auto-Injector (b) (4)

Indication: Acute migraine with or without aura/acute cluster headache in adults

Applicant: King Pharmaceuticals, Inc.

Review Division: Neurology Products

Reviewer: D. Charles Thompson, R.Ph., Ph.D., D.A.B.T.

Supervisor/Team Leader: Lois Freed, Ph.D.

Division Director: Russell G. Katz, M.D.

Project Manager: Lana Chen

Disclaimer:

NME: N/A

505(b)(2): Yes (substantially equivalent, standard review)

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1. Executive Summary

1.1. Recommendations

1.1.1. From a nonclinical perspective, it is recommended that the application be approved as submitted.

1.1.2. It is recommended that nonclinical aspects of approved labeling for the RLD be adopted and incorporated into labeling for the proposed drug product without modification.

1.2. Regulatory background:

NDA 22-377 was received by the Agency on 17 July 2008. This is a 505(b)(2) application in which the proposed product differs from the approved RLD product, Imitrex®, only in the design and operating principles of the proposed injection delivery device. The drug substance, proposed indications, and targeted population are identical to those of the RLD product. The proposed drug product (b) (4) is composed of a pre-filled, disposable, single-use 'autoinjector', which differs from the approved Imitrex® product with its STATdose® system that requires assembly of a prefilled cartridge with the non-disposable STATdose® injector, and disassembly after use. The proposed (b) (4) product is a single-use device that is completely disposable; its use involves removal of the device from its storage case, removal of the safety pin, placement of the needle end of the device against the injection site and application of pressure until the device actuates. The device is then held in place for 5 seconds while the drug is delivered.

1.3. Overall integrated summary and safety evaluation:

The clinical review team has concluded that the proposed use (dose, dosing regimen, and indication) falls within the domain of the approved RLD dosing regimen(s) and does not represent an increase in exposure to drug or target a different patient population. The submitted application contains no new nonclinical pharmacology/ toxicology data and none were required, as the sponsor relies on the Agency's previous safety decisions—as well as data and information contained within approved labeling—for the RLD product. For the nonclinical and safety sections of the label, the sponsor proposes to use the current RLD (i.e., Imitrex®) labeling. This is considered adequate for the drug substance; and since no unusual excipients are used in the new formulation, there are no nonclinical objections to approval.

Thus, it is recommended that, from a nonclinical perspective, the application be approved as submitted and that approved labeling from the RLD be adopted without modification.

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/s/

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5/11/2009 12:02:59 PM
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