CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022377Orig1s000

SUMMARY REVIEW

Cross-Discipline Team Leader Review

Date	June 16, 2010
From	Eric Bastings, MD
Subject	Cross-Discipline Team Leader Review
NDA/BLA # Supplement#	22-377
Applicant	King Pharmaceuticals, Inc.
Date of Submission	December 23, 2009
PDUFA Goal Date	June 29, 2010
Proprietary Name / Established (USAN) names	Alsuma (sumatriptan) injection
Dosage forms / Strength	6mg/0.5ml injection
Proposed Indication(s)	Acute treatment of migraine
Recommended:	Approval

King Pharmaceuticals submitted a 505(b)(2) application for a new pre-filled, single-use disposable auto-injector product containing 6 mg of sumatriptan succinate delivered in a 0.5 mL subcutaneous dose. This application was issued a complete response letter in the first cycle. I refer the reader to my May 5, 2009 memorandum, that describes the key review issues identified in the first cycle. As the tradenames proposed by the sponsor were rejected by FDA in the first cycle, the division was concerned about possible inadvertent substitution of this product with other sumatriptan autoinjectors, which may lead to administration errors and/or failure, as instructions for use are not the same. I copy below the relevant paragraph from the action letter regarding the reason for the complete response action:

INSUFFICIENT INFORMATION ABOUT THE DRUG TO DETERMINE WHETHER THE PRODUCT IS SAFE FOR USE UNDER THE CONDITIONS PRESCRIBED, RECOMMENDED, OR SUGGESTED IN ITS PROPOSED LABELING (21CFR § 314.125 (B)(4)).

We believe that a proprietary name is necessary to assure safe and effective use of your product, and prevent medication errors, for the following reasons:

Your 6 mg sumatriptan succinate auto-injector differs from the previously approved Imitrex 6 mg (sumatriptan succinate) auto-injector in that your product, among other things, is a preassembled single use disposable injector. It is operated by grasping the device in the middle and applying pressure to push the needle end against the injection site. By contrast, the Imitrex auto injector is a reusable device that must be individually loaded before each use. It operates by pushing a button at the end of the device. Your proposed labeling, and the approved labeling of the Imitrex auto-injector, includes statements directing prescribers to instruct patients on the proper use of the product prior to first use in a medically unsupervised situation. Given that patients instructed on the use of another sumatriptan auto-injector may be unable to use your product without prior training, inadvertent substitution may lead to failed use of your product during a migraine attack, or to a safety risk to the patient.

As communicated to you during the review cycle, both proposed proprietary names were found unacceptable by the Agency. As you have not proposed an alternative acceptable proprietary name, or evidence that your product is safe for use without a proprietary name, the application can not be approved.

During this second review cycle, the proposed tradename “Alsuma” was accepted by the Agency. This resolved the issue that led to the complete response action. Therefore, I recommend approval for this product. Final labeling contents are being negotiated.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22377	ORIG-1	KING PHARMACEUTICALS INC	SUMATRIPTAN SUCCINATE AUTO-INJECTOR

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/s/

ERIC P BASTINGS
06/16/2010