DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-377 **NDA APPROVAL**

King Pharmaceuticals, Inc.
Attention: Mr. Greg Carrier
501 Fifth Street
Bristol, TN 37620

Dear Mr. Carrier:

Please refer to your New Drug Application (NDA) dated December 23, 2009, received December 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alsuma (sumatriptan) 6mg/0.5ml injection.

We acknowledge receipt of your 2010 submissions dated January 11, March 18 and June 4.

The December 23, 2009 submission constituted a complete response to our May 25, 2009 action letter.

This new drug application provides for the use of Alsuma (sumatriptan) injection for the acute treatment of migraine headache.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, and text for the patient instructions for use). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We note that you have agreed to the following revisions regarding your container labels, carton labeling, and instructions for use:

A. General Comments

These comments pertain to all the labels and labeling. Please revise accordingly.

1. The product strength appears within the parenthesis in conjunction with the established name. Increase the prominence of the product strength by relocating it so it appears beneath the established name and not in the parenthesis. Additionally increase the size of the strength.

B. Container Label

1. See General Comments.
2. Because the label is small, decrease the prominence of the distributor name and the graphic of the globe in order to give more prominence to more pertinent information on the label.

C. Carton Labeling

1. See General Comments.
2. The distributor name and logo have greater prominence than the route of administration; therefore, decrease the prominence of the distributor name and increase the size of the route of administration in order to give more prominence to more pertinent information on the label.
3. Debold the phrase "Auto-Injector" as it appears more prominent than the established name. The phrase "Auto-Injector" should not have more prominence than the established name.

Submit final printed carton and container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved NDA 22377." Approval of this submission by FDA is not required before the labeling is used.

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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

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

/s/

LANA Y CHEN
06/29/2010

RUSSELL G KATZ
06/29/2010