DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-933

JUL 29 2005

Strategic Bioscience Corporation
Attention: Dr. James Parker
President
U.S. Agent for: Cobalt Pharmaceuticals, Inc.
93 Birch Hill Road
Stow, MA 01775

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 4, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Sumatriptan Succinate Tablets, 25 mg (base), 50 mg (base) and 100 mg (base).

Reference is also made to your amendments dated July 28, 2004; and February 3, February 7, March 30, April 27, and May 3, 2005. We also acknowledge receipt of your correspondence dated April 7, 2004, regarding the patent issues noted below.

We have completed the review of this ANDA, based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, your ANDA is not eligible at this time to receive final approval because of the patent issue discussed below. Therefore, your ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is also subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your ANDA, Imitrex Tablets, 25 mg (base), 50 mg (base) and 100 mg (base), of GlaxoSmithKline is subject to multiple periods of patent protection. The following patents and expiration dates (with

pediatric exclusivity added) are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
4,816,470 (`470 patent)	June 28, 2007
5,037,845 (`845 patent)	February 6, 2009
5,863,559 (`559 patent)	July 26, 2016
6,020,001 (`001 patent)	September 2, 2012
6,368,627 (`627 patent)	September 2, 2012

Your ANDA contains a paragraph III patent certification under section 505(j)(2)(A)(vii)(III) of the Act to the '470 patent. This certification states that Cobalt Pharmaceuticals, Inc. will not market Sumatriptan Succinate Tablets under this ANDA prior to the expiration of the '470 patent (6/28/07).

Your ANDA also contains paragraph IV patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the `845, `559, `001 and `627 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Sumatriptan Succinate Tablets under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless action is brought against Cobalt Pharmaceuticals, Inc. (Cobalt) for infringement of one or more of the patents that were the subjects of paragraph IV certifications. This action must have been brought against Cobalt prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B) was received by the NDA/patent holder(s). You notified the agency that Cobalt complied with the requirements of section 505(j)(2)(B) of the Act, and that patent infringement litigation was brought against Cobalt in the United States District Court (b)(4) (b)(4) alleging infringement of the '845 patent (b)(4)

Therefore, final approval cannot be granted under section 505(j)(5)(B)(ii) of the Act until the '470 patent has expired (with pediatric exclusivity added), i.e., June 28, 2007, and:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii)[1] or such shorter or longer period as the court may have ordered, or,

   b. the date a court decides[2] that the '845 patent is invalid or not infringed (see section 505(j)(5)(B)(iii)(I), (II), and (III)], of the Act), or,

   c. the '845 patent has expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices

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[1] Because information on the '845, '559, '001, and '627 patents was submitted before August 18, 2003, this reference is to a section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

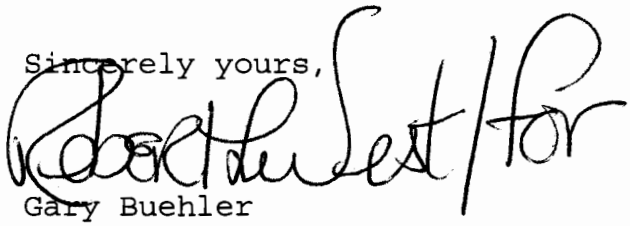
[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

(cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act and 21 U.S.C. 331(d). Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under 21 U.S.C. 355, and will not be listed in the "Orange Book".

For further information on the status of this application, or prior to submitting additional amendments, please contact Ted Palat, Project Manager, at 301-827-5849.

Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research