ANDA 75-442

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

TO: APPLICANT: King and Spaulding
U.S. Agent for Alphapharm Pty. Ltd.

ATTN: Christine Markus

TEL: 202-626-2926

FAX: 202-626-3737

PROJECT MANAGER: 301-827-5849

FROM: Bonnie McNeal

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated July 16, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Flecainide Acetate Tablets USP, 50 mg, 100 mg and 150 mg.

We are pleased to inform you that this application is APPROVED!
Congratulations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 75-442

Food and Drug Administration
Rockville MD 20857

JUL 31 2001

King and Spalding
U.S. Agent for Alphapharm Pty. Ltd.
Attention: Eugene Pfeifer
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Dear Sir:

This is in reference to your abbreviated new drug application dated July 16, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Flecainide Acetate Tablets USP, 50 mg, 100 mg and 150 mg.

Reference is also made to your amendments dated September 10, and November 13, 1998; and April 17, June 28, July 25, and July 30, 2001.

The listed drug product (RLD) referenced in your application, Tambocor™ Tablets of 3M Pharmaceuticals, Inc., is subject to a period of patent protection which expires on February 10, 2004, (Patent No. 4,642,384). Your application contains a Paragraph IV Certification to the '384 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. This certification states that your manufacture, use, or sale of the drug product will not infringe on the patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Alphapharm Pty. Ltd. (Alphapharm) for infringement of the patent that is the subject of the certification (the '384 patent). You have notified the agency that Alphapharm has complied with the requirements of Section 505 (j)(2(B) of the Act. As a result, 3M Pharmaceuticals, Inc. (3M) initiated a patent infringement suit against you in the United States District Court for the District of Minnesota (Minnesota Mining and Manufacturing Company and Riker Laboratories, Inc. v. Alphapharm Pty. Ltd., Civil Action No. 99-13 JMR/FLN). You have also informed us that 3M and Riker requested an extension of the statutory 30-month stay of approval in the patent infringement

litigation, and that the request was denied on June 8, 2001, in a non-appealable district court order.

Although the patent infringement litigation is ongoing, the Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Flecainide Acetate Tablets USP, 50 mg, 100 mg, and 150 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Tambocor™ Tablets 50 mg, 100 mg, and 150 mg, respectively, of 3M Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

With respect to 180-day generic drug exclusivity, we note that Alphapharm Pty. Ltd. (Alphapharm) was the first applicant to submit a substantially complete ANDA with a Paragraph IV Certification to the '384 patent for this drug product. Therefore, with this approval Alphapharm is eligible for 180-days of market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. Such exclusivity will begin to run either from the date Alphapharm begins commercial marketing of the drug product, or in the absence of marketing, from the date of a decision of a court finding the patent invalid or not infringed whichever event occurs earlier [Section 505(j)(5)(B)(iv)].

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of the court holding the relevant patent invalid, unenforceable or not infringed.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible

for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710). You may also refer to the agency's draft guidance entitled "Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act" (March 2000).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

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