NDA 19-979/S-018

Syntex (U.S.A.) LLC
c/o Hoffmann-La Roche Inc.
Attention: Ms. Lynn DeVenezia-Tobias
340 Kingsland Street
Nutley, New Jersey 07110-1199

18 APR 2001

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated January 20, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ticlid (ticlopidine hydrochloride) Tablets.

We acknowledge receipt of your submissions dated November 28, 2000 and January 5, February 16 and March 20, 2001. Your submission of March 20, 2001 constituted a complete response to our November 22, 2000 action letter.

This supplemental new drug application provides for the new use of Ticlid (ticlopidine hydrochloride) Tablets as adjunctive therapy with aspirin to reduce the incidence of subacute stent thrombosis in patients undergoing successful coronary stent implantation.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and patient package insert included in your March 20, 2001 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). As noted in our February 4, 2000 acknowledgement letter for this application, we have waived the pediatric study requirement for this application.

Please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Colleen LoCicero
Regulatory Health Project Manager
(301) 594-5332

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research