DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS
FOOD AND DRUG ADMINISTRATION

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Transmitted to FAX Number: 415-514-2119

Attention: John

Phone:

Subject: IND 100,915

Date: Dec. 21, 2007

Pages including this sheet: 3

From: Khinmaung Zaw
Phone: 301-796-1037
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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND 100,915

S. Claiborne Johnston, M.D., MPH, Ph.D.
Director, Stroke Service
University of California, San Francisco
Department of Neurology, Box 0114
505 Parnassus Avenue, M-798
San Francisco, CA 94143-0114

Dear Dr. Johnston:

The Center for Drug Evaluation and Research has received your Investigational New Drug Application (IND). The following product name and IND number have been assigned to this application. They serve only to identify it and do not imply that this Center either endorses or does not endorse your application.

IND #: 100,915

SPONSOR: S. Claiborne Johnston, M.D., MPH, Ph.D.

PRODUCT NAME: Clopidogrel

DATE OF SUBMISSION: October 26, 2007

DATE OF RECEIPT: November 15, 2007

The Food and Drug Administration published revised New Drug, Antibiotic, and Biologic Drug Product Regulations in the Federal Register (52 FR 8798-8847), on March 19, 1987, which became effective June 19, 1987. Those regulations, which apply to all clinical investigations of products that are subject to section 505 (new drugs) or section 507 (antibiotics) of the FFD&C Act or to the licensing provisions of the Public Health Service Act (biological products), state that the clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the IND requirements if all of the following apply:

1. The route of administration, dosage level, patient population, and other factors do not significantly increase the risks or decrease the acceptability of the risks, and

2. Informed patient consent is secured (21 CFR Part 50), and

3. The study is not begun until it has been reviewed and approved by, and remains subject to continuing review by, an Institutional Review Board (IRB) meeting the requirements of Section 56 of Part 21 of the Code of Federal Regulations (21 CFR Part 56), and

4. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use; or intended to be used to support any other significant change in the labeling or, for prescription drug products, a significant change in the advertising for the drug, and

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5. The investigation is conducted in compliance with the requirements of 21 CFR 312.7, i.e., the investigational drug may not be represented as safe or effective for the purposes for which it is under investigation nor may it be commercially distributed or test marketed nor may it be sold.

The use of a placebo does not mandate an IND if the study would not otherwise require one.

Upon review of the information contained in your submission for the treatment in reducing the 90 day risk of stroke, myocardial infraction, and vascular death (the primary composite outcome) when initiated within 12 hours of TIA onset in pts receiving aspirin, we conclude that your study meets all of the requisites set forth at 21 CFR 312.2(b)(l), and, accordingly, that it is exempt from the requirements of Part 312 of the IND regulations. Therefore, as mandated by 21 CFR 312.2(b)(4), FDA will not accept this application.

We remind you that exemption from the requirements for an IND does not include exemption from the requirements for informed patient consent, and initial and continuing IRB review and approval.

If you wish to contact us in writing regarding this application please reference the IND number above and use the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardiovascular and Renal Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions concerning this IND, please contact:

Mr. Edward Fromm
Chief, Project Management Staff
(301) 796-1072

Sincerely yours,

{See appended electronic signature page}

Norman Stockbridge
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research