DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-l 448

Our Reference Nos: 97-0200 and 97-0202 **November 5, 1997**

John H. Parker, Ph.D.
Centocor B.V.
Einsteinweg 101, P.O. Box 251
2300 AG Leiden
The Netherlands

Dear Dr. Parker:

Your requests to supplement your biologic license application for Abciximab to expand the indication, to provide for revised dosage and patient management guidelines to reduce bleeding, and to include additional information on readminstration have been approved. The indication now includes treatment of a broad range of patients undergoing percutaneous coronary intervention and patients with unstable angina not responding to conventional medical therapy when percutaneous coronary intervention is planned within 24 hours.

We acknowledge your commitment of October 22, 1997, to conduct and complete a Phase 4 clinical trial to further investigate the readministration of ReoPro™. The objectives of this study will include an evaluation of the frequency, magnitude and duration of any HACA response after readministration and an evaluation of readminstration to patients who are HACA positive.

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

This information will be included in your biologic license application file.

Sincerely yours,

Patricia Keegan for Dr. Weiss

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
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cc: Mr. Martin Page
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