DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103575/5025

NOV 21 2003

Centocor, B.V.
Attention: Kim Shields-Tuttle
Director, Worldwide Regulatory Affairs
200 Great Valley Parkway
Malvern, PA 19355-1307

Dear Ms. Shields Tuttle:

Your request to supplement your biologics license application for Abciximab to revise the Precautions section to include the effect of readministration on HACA rates, clinical outcome, serious allergic reactions and thrombocytopenia, and to delete readministration information on healthy volunteers has been approved.

This fulfills your commitment to conduct and complete a Phase 4 clinical trial to further investigate the readministration of Abciximab as stated as part of commitment number 1 of the December 22, 1994 approval letter and as restated in commitment number 1 of the November 5, 1997 approval letter.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see http://www.fda.gov/cber/transfer/transfer.htm and http://www.fda.gov/OHRMS/DOCKETS/98fr/03-16242.html. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

CBER Document Control Center
Attn: Office of Therapeutics Research and Review
Suite 200N (HFM-99)
1401 Rockville Pike
Rockville, Maryland 20852-1448

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

Sincerely,

(b)(6) [redacted]

Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Office of New Drugs
Center for Drug Evaluation and Research

Enclosures