DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

STN: BL 125166/33 June 30, 2008

Alexion Pharmaceuticals
Attention: Arthur D. Edwards
Executive Director, Regulatory Affairs
352 Knotter Drive
Cheshire, CT 06410

Dear Mr. Edwards:

Your request to supplement your biologics license application for Soliris® to revise your United State Package Insert based upon postmarketing safety experience, specifically related to meningococcal infection, has been approved.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

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

If you have any questions, contact Ebla Ali Ibrahim, Regulatory Project Manager, at (301) 796-3691.

Sincerely,

Rafel Rieves, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research