Product Approval Letter - OLYMPUS PK system Blood Grouping and Phenotyping Reagents

Product Approval Information - Licensing Action

January 10, 2008

Our STNS: SEE BELOW

Olympus America, Inc.
Attention: Ms. Raya Zerger
Authorized U.S. Agent for Diagast
3131 W. Royal Lane
Irving, TX 75063

Dear Ms. Zerger:

We are issuing Department of Health and Human Services U.S. License No. 1744 to DIAGAST, Loss Cedex, FRANCE under the provisions of section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes Diagast to introduce or deliver for introduction into interstate commerce, those products for which the company has demonstrated compliance with establishment and product standards.

Under this license, Diagast is authorized to manufacture the Blood Grouping Reagents and Reagent Red Blood Cells listed below. These products are indicated for the in vitro detection and identification of human blood group antigens by direct agglutination.

Our Submission Tracking Numbers (STN)	Name of Biological Product	Cell Line(s)
BL 125169/0	Blood Grouping Reagent, Anti-A (Murine Monoclonal) (Formulated for Automated Testing)	2521B8 and 16243G2
BL 125169/0	Blood Grouping Reagent, Anti-A (Murine Monoclonal) (Formulated for Automated Testing)	9113D10
BL 125170/0	Blood Grouping Reagent, Anti-B (Murine Monoclonal) (Formulated for Automated Testing)	9621A8
BL 125170/0	Blood Grouping Reagent, Anti-B (Murine Monoclonal) (Formulated for Automated Testing)	164B5G10 and 7821D9
BL 125171/0	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal) (Formulated for Automated Testing)	2521B8, 16243G2, 16247E10 and 7821D9
BL 125172/0	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM) (Formulated for Automated Testing)	P3X61
BL 125172/0	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM) (Formulated for Automated Testing)	HM10
BL 125173/0	Blood Grouping Reagent, Anti-D (Monoclonal Blend) (Formulated for Automated Testing)	P3X61, P3X21223B10, P3X290 and P3X35
BL 125174/0	Blood Grouping Reagent, Anti-E (Monoclonal) (Formulated for Automated Testing)	906
BL 125175/0	Blood Grouping Reagent, Anti-C (Monoclonal) (Formulated for Automated Testing)	P3X25513G8 and MS24
BL 125176/0	Blood Grouping Reagent, Anti-e (Monoclonal) (Formulated for Automated Testing)	MS63 and P3GD512
BL 125177/0	Blood Grouping Reagent, Anti-c (Monoclonal) (Formulated for Automated Testing)	951
BL 125186/0	Blood Grouping Reagent, Anti-K (Monoclonal) (Formulated for Automated Testing)	MS56

Submission Tracking Number (STN)	Name of Biological Product
BL 125168/0	Reagent Red Blood Cells For Use in Automated Systems (A_1 and B cells)

Under this license, Diagast is approved to manufacture Blood Grouping Reagents and Reagent Red Blood Cells at their facility in Loos Cedex, FRANCE. Diagast may label the Blood Grouping Reagents with the proprietary name OLYMPUS® PK® SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS and market them in 20 mL or 30 mL screw-cap ---------- vials, as specified in the applications. Diagast may label the Reagent Red Blood Cells with the proprietary name OLYMPUS® PK® SYSTEM REAGENT RED BLOOD CELLS (A1and B) and market them in 20 mL volumes in 60 ml ------ vials or 30 mL volumes in 50 ml ----- vials, as specified in the applications.

The dating period for the OLYMPUS® PK® SYSTEM BLOOD GROUPING REAGENTS shall be 21 months from the date of manufacture when stored at 2 - 8 °C. The date of manufacture of blood grouping reagents made from Diagast ---------- shall be defined as the date of ---------- of the ----------. The date of manufacture of blood grouping reagents made from ---------- stored at -------- °C shall be defined as the date of formulation of the bulk product. The dating period for the OLYMPUS® PK® SYSTEM REAGENT RED BLOOD CELLS (A1and B) shall be 45 days from the date of manufacture when stored at 2-8 °C. The date of manufacture shall be defined as the date of diluting the packed red blood cells with Alsever's solution. **Following the final filtration of the Blood Grouping Reagents or the final dilution of the Reagent Red Blood Cells, no reprocessing is allowed without prior approval from the Agency.**

Please submit samples of the Blood Grouping Reagents in final containers together with protocols showing results of all applicable tests. Diagast may not distribute any lots of Blood Grouping Reagents until they receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER). Routine submission of samples and test results with subsequent release by the Director, CBER is not required for Reagent Red Blood Cells for reverse grouping.

Diagast must submit information to the biologics license applications for our review and written approval under 21 CFR 601.12 for any changes in the manufacturing, testing, packaging or labeling of the Blood Grouping Reagents or Reagent Red Blood Cells, or in the manufacturing facilities.

We acknowledge your written commitments on behalf of Diagast as described in your letter of November 12, 2007 as outlined below:

Postmarketing Studies not subject to reporting requirements of 21 CFR 601.70.

1. ----------

Submit adverse experience reports in accordance with the Medical Device Reporting requirements for medical devices (21 CFR 803) as required by (21 CFR 600.81(k)(2)). Since these products are characterized as devices as well as biological products, submit these reports to the MedWatch System using MedWatch Reporting Form 3500A. Required reports should be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, Maryland 20847-3002.

Diagast must submit reports of biological product deviations under 21 CFR 600.14. They promptly should identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, they must submit a report on Form FDA-3486 to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h and FDA Form 2567 as appropriate. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Two copies of final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have submitted data to support such claims to us and had them approved.

Sincerely yours,

/Mary A. Malarkey/
Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

/Jay S. Epstein, MD/
Jay S. Epstein, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research