



Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

Mr. Philippe Monod  
Medion Diagnostics AG  
Bonnstrasse 9  
CH-3186 Dudingén  
Switzerland

July 12, 2006

Dear Mr. Monod:

We have been advised by your letter of March 29, 2006, that your company, formerly identified as Medion Diagnostics GmbH, U.S. License No. 1616, is now identified as Medion Diagnostics AG.

It is our understanding that Medion Diagnostics AG, will continue to prepare Reagent Red Blood Cells in the same manner as Medion Diagnostics GmbH, using the same equipment, manufacturing procedures and methods, and responsible personnel. It is also our understanding that you will be the authorized official for Medion Diagnostics AG.

The appropriate license applications and other information required for the change in licensure have been reviewed, and found to be in compliance with the required standards. Therefore, in accordance with the provisions of Title 21 Code of Federal Regulations Section 601.5(a), U.S. License No. 1616 is hereby revoked, effective this date.

In addition, in accordance with the provisions of Section 351(a) of the Public Health Service Act, U.S. License No. 1740 is hereby issued to Medion Diagnostic AG, Dudingén, Switzerland, effective this date. This license authorizes you to manufacture and introduce or deliver for introduction into interstate commerce those products for which you have demonstrated compliance with establishment and product standards.

Under this license you are authorized to manufacture and introduce or deliver for introduction into interstate commerce Reagent Red Blood Cells manufactured at your Dudingén, Switzerland, location.

Please submit final printed labels for each product you are authorized to manufacture at this location showing your new corporate name and the license number to the Division of Blood Applications (HFM-390). Labeling revisions reflecting the new name of your establishment should be completed within 180 days of receipt of this letter.

All pending supplements submitted under U.S. License No. 1616 have been transferred to U.S. License No. 1740. All future correspondence for these submissions should be submitted under the originally assigned Submission Tracking Number BL 103898 for your Biologics License Application for Reagent Red Blood Cells.

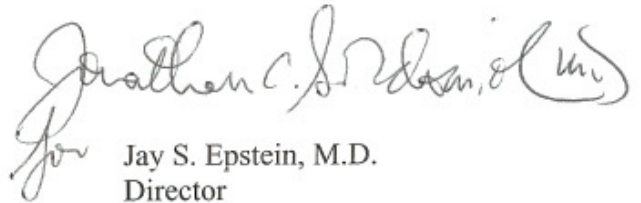
Please note that this letter supersedes any previously issued license certificates. These certificates may be placed in your historical files. We recommend that a copy of this letter be available at the referenced location for review at the time of FDA inspections.

We request that you acknowledge receipt of this letter to the Director, Division of Manufacturing and Product quality, HFM-670, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448.

Sincerely yours,



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



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