OMRIX Biopharmaceuticals, Ltd.
Attention: Sara Horn, PhD
14 Einstein Street, Weizmann Science Park
P.O. Box 619
Rehovot, 76106
Israel

Dear Dr. Horn:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

Our Submission Tracking Number (STN): BL 125392/0

Name of Biological Product: Fibrin Pad

Indication: An adjunct to hemostasis for soft tissue bleeding during retroperitoneal, intra-abdominal, pelvic, and (non-cardiac) thoracic surgery when control of bleeding by standard surgical methods of hemostasis is ineffective or impractical

Date of Application: November 15, 2010

Date of Receipt: November 19, 2010

Action Due Date: September 19, 2011

US License Number and Manufacturing Site: 1603

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have not fulfilled the requirement. We acknowledge receipt of your request for a deferral of pediatric studies in children less than 16 years of age for this application. Once the application has been filed, we will notify you whether we have deferred the pediatric study requirement for this application.

Please note that you are also responsible for complying with the applicable provisions of sections 402(i) and (j) of the Public Health Service Act (PHS Act) (42 U.S.C. §§ 282(i) and (j), which