



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

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

was recently amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No. 110-85, 121 Stat.904).

We request that you submit all future correspondence, supporting data, or labeling relating to this application in triplicate, citing the above STN number. Send all correspondence to the following address:

Richard J. Davey, M.D., HFM-370
DCC, Suite 200N, HFM-99
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Applicants who sent applications via the Food and Drug Administration Electronic Submissions Gateway (ESG) should continue to use those procedures. The ESG is an Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

CBER strongly encourages the use of secure email. Secure email makes use of encryption during transmission and the messages are decrypted upon receipt using the certificate. To establish secure email, please follow the instructions in *SOPP 8119: Use of Email for Regulatory Communications*, Appendix 1 or Appendix 2.

CBER may communicate with you via non-secure email if you provide written authorization to do so. Authorization is file specific; please submit new authorization for each file and/or submission you hold with CBER.

Please note that CBER will only use email in place of telephone communications for general discussions, to relay regulatory issues and to request information. CBER will not provide copies of letters or meeting minutes by email and will not usually accept regulatory submissions via email.

We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

If you have any questions, please contact me at (301) 827-6122.

Sincerely yours,

Sonday L. Kelly
Regulatory Project Manager
Division of Blood Applications
Office of Blood Research and Review
Center for Biologics
Evaluation and Research