

MEMORANDUM



Department of Health and Human Services
Public Health Service
United States Food and Drug Administration
Center for Biologics Evaluation and Research



To: File (STN 125392/0 Original BLA Evarrest™)

From: La’Nissa A. Brown-Baker, Ph.D., Pharmacologist, Division of Hematology (DH)/OBRR

Through: Iftekhar Mahmood, Ph.D., Team Lead, DH/OBRR

For: Filing for Original BLA STN 125392/0- Omrix’s Fibrin Pad Evarrest™

This memorandum summarizes the preliminary non-clinical review of original biological license application (BLA) for Evarrest™, Fibrin Sealant Pad, indicated as adjunct to hemostasis for mild to moderate bleeding for soft tissue during retroperitoneal, intra-abdominal, pelvic and (non-cardiac) thoracic surgery when standard surgical methods of hemostasis are ineffective or impractical. The STN 125392 BLA for Omrix’s Fibrin pad, Evarrest™, does appear to be fileable based on preliminary review of the pharmacological and toxicological data presented.

However, there are some pre-clinical program deficiencies that should be addressed by the sponsor including:

- Incomplete pre-clinical study reports that are referenced in BLA
- Lack of submission of data that addresses the complete absorption of final clinical grade product using pre-clinical or clinical findings
- Risk assessment analysis for carcinogenic potential from product use
- Repeat-dose toxicity data for multiple/subsequent use of product
- Potential of immunogenicity following product use

These deficiencies must be addressed by the Sponsor prior to approval of BLA completion.