

Report of Telephone Conversation - EVARREST, June 7, 2011

Date/Time of Call :	June 7, 2011
CBER Representatives:	Randa Melhem, CMC Reviewer/Inspector, OCBQ/DMPQ Marion Michaelis, Team Lead, OCBQ/DMPQ
Organization Representatives:	Susan Miller, VP QA Omrix Christie Bielinski, Group Director, Quality and Compliance J&J Wound Management Paul Fitton, Cleaning and Shipping Validation Lead Dieter Bachmann, Quality Site Lead, Jerusalem Plant
Organization:	Omrix Biopharmaceuticals Ltd. / Ethicon Inc.
Telephone:	----(b)(4)----
Subject:	Discussion about the 483 observation regarding (b)(4) acceptance limits of -----(b)(4)----- of equipment.
STNs:	125392/0

Background:

During the PLI (May 10-19, 2011), Omrix was cited on the FDA form 483 that “the acceptance criterion for -----
-(b)(4)----- Use of this criterion would allow for potential unclean equipment to be utilized in the next production run”. Omrix/Ethicon requested a telecon with FDA to discuss the intent of this section of the observation: *allow for potential unclean equipment to be utilized in the next production run.*

Telecon

During the telecon, FDA reiterated that the acceptance criterion is too high, and that if the equipment is clean, the ----(b)(4)---- should meet (b)(4) specifications ---(b)(4)---.

FDA added that the (b)(4) specifications should be set based on the cleaning procedure capabilities, and in line with (b)(4) specifications. Omrix/Ethicon clarified that ----(b)(4)---
- specification has been set according to the -----(b)(4)----- guideline and is considered to ensure both safety and cleanliness. They added that they will review their historical data, and would adjust the (b)(4) acceptance criterion to align with the capability of the cleaning process to ensure better control.