

**Thomas, Terrolyn**

---

**From:** Streun, Ed [EStreun@NYBloodCenter.org]  
**Sent:** Monday, January 31, 2011 1:19 PM  
**To:** Thomas, Terrolyn  
**Cc:** Ghosh, Joydeep; Quagraine, Mercy  
**Subject:** RE: Sterility Assay Validation - information request

Ms. Thomas,  
 Good afternoon. I confirm receipt and have passed on your request.

Regards,  
 Ed Streun

**From:** Thomas, Terrolyn [mailto:Terrolyn.Thomas@fda.hhs.gov]  
**Sent:** Monday, January 31, 2011 11:27 AM  
**To:** Streun, Ed  
**Cc:** Ghosh, Joydeep; Quagraine, Mercy  
**Subject:** FW: Sterility Assay Validation - information request

Hello Mr. Streun:

We are unable to access the contents of the following under Section 4.3.2.1 of your BLA 125397.

1. NCBP-VAL-10-006P-Add1
2. NCBP-QPP-QC-(b)(4)
3. NCBP-VAL-09-015
4. NCBP-VAL-10-003
5. NCBP-VAL-10-006
6. NCBP-VAL-10-00
7. SOP OP E6
8. SOP CB40.007.1

We also need the following information on your used (b)(4) system:

9. Detailed description including model name/number and Working Principle of the system
10. Names and detailed composition of all culture media
11. System Installation and Operation Qualification reports

Please send the requested information as an official supplement to your BLA 125397 as soon as possible so we can proceed with our review. Please confirm receipt of this email.

Thank you very much.

Regards,  
 Terrolyn

***Terrolyn B. Thomas, MS, MBA***

11/30/2011

Regulatory Project Manager  
OCTGT/CBER/FDA  
Phone: 301-827-9161  
Terrolyn.Thomas@fda.hhs.gov