# Correspondence Detail Report

16-NOV-2009

CBER 510(k), PMA, and PMS Submissions

| | |
|---|---|
| **Submission ID** BN080041 | **Date Rec. In CBER:** 04-AUG-2008 |
| **Supplement ID:** 0 | **Document Date** 31-JUL-2008 |
| **Submission Type** NDA | **Due Date:** 12-DEC-2009 |
| **Status:** Response Review | **Responsible Organization:** DBA |
| **Applicant Firm:** Fenwal Inc | **DCC Login ID:** 446481 |
| **Product:** AAA unidentifiable product | |

**Originator:** FDA

**Correspondence DCC Login ID:**

**Correspondence Type:** Telecon

**Due Date Changed:** N

**CBER Received Date:** 03-NOV-2009

**Document Date:** 03-NOV-2009

**Correspondence Purpose(s):** Conversation record

**Applicant Contact Person(s):** Ms. Cheryl Chamberlain Roscher,

**FDA Participant(s):** Heather Erdman, OBRR APPROVED

**Summary:** T-con - 03Nov09 - Sterilization

**Comments:** BN080041 - T-con - 11/3/09 - Sterilization
Fenwal Attendees: Cheryl Roscher; Ariel Gonzales (plant); Isa Klein; Ivellsse Betancourt (plant); Peyton; Laura S.; Brian Mc Mullen
CBER Attendees: Heather Erdman; Randa Melhem; Salim Haddad

CBER's concerns:
" The Fo data provided by Fenwal are for Fo studies performed in vessel b(4)
o All of the data does not have to be from vessel b(4), although data is required to support Fo studies for InterSol in vessel b(4) to support an Fo= b(4)
o After b(4) minutes the b(4) vessels demonstrated a b(4) minute difference
" Several factors were different in the studies: vessel, product/ packaging (container-closure)
" The acceptance criteria for the min Fo has to be in the range of the data provided in the submission and subsequent response.
c b(4) validation studies supported a range of b(4)
o A value of b(4) is very low, not standard; a range of b(4) is very wide. Data is required to support such a range
o Perhaps consider a range of b(4)
o Data should be provided to support the lowest of range of temp and lowest range of time; provide data to support the kill
" The data provided for the additional b(4) amicus studies show b(4) location in the b(4) b(4) This is no longer an issue as CBER has mapped this out and considers that in time more data will be generated.

Fenwal's perspective:
" Fractionals are not vessel dependent
" Solution contained for investigational device is same; difference is closure; the closure for the investigational device is more complex; the configuration btw the two is the same

" Fenwal keeps tight control over the vessels: b(4) Fractionals provided to show you that when you go out of the b(4) range you will still get the kill that you would expect.
" Fo is a computed value; a range of b(4) would not be possible. A range of b(4) would require a temp of b(4); therefore reject good material.
" Guidance - acceptable differences to drug products - a move from one vessel to another is consideration a minor change. Fenwal did the validation/ qualification studies (which are the studies recently provided to CBER) to support this
" Confused because provided this data in a previous application (b(4) (Intersol; part of b(4)) that was not approved; approval issues not related to this issue), and no issues were brought up about this cycle. This has been Fenwal's practice for 30 years.

Agreed upon action plan:
Fenwal will propose new limits based on limits set on exposure (as opposed to total time) and provide the calculations to support these limits. This will be provided by COB Wed 04Nov09.

Note: Fenwal agrees that b(4) would be expected, yet they can get lowest Fo (considering b(4) b(4) highest b(4). They have done calculations based on exposure as opposed to total time which will be higher.