Correspondence Detail Report

16-NOV-2009

CBER 510(k), PMA, and PMS Submissions

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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: 11-AUG-2009

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Correspondence Purpose(s): Conversation record

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

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APPROVED

Summary: DMPQ's review of Fenwal's resp to CMC issues/IR Fax from their complete response

Comments: Purpose: To discuss the recent FDA IR faxes pertaining to Fenwal's complete response (dated 20Jul09). This conversation pertained to DMPQ's review of Fenwal's response to CMC issues/IR Fax from their complete response (dated 31Jul09).

FDA: Q2 & Q6; related to same issue: how did Fenwal map the autoclave (no cold or hot spots)? Fenwal explained that they have a b(4) sterilizer as opposed to b(4) did a b(4) mapping; used a b(4) map distribution to show an even distribution, also did a b(4) distribution in b(4) location in the empty chamber, to show b(4) nominal difference.

FDA: how many times was this repeated? Fenwal: studies were done with initial b(4) with and empty chamber and a full load (b(4) 1432 & 1431). Empty chamber studies and probing is prior to qualification and then follow product qualification during which even temp distribution is shown again. Verify that they maintained appropriate temps and got appropriate kill levels. Two studies in b(4) are not done in isolation. Chamber is adequate prior to product qualification. This is not just used for InterSol but for other products (different cycles). This is the same type of qualification that has been used and approved since initial parametric release and approval in 1999; same technique for all of Fenwal's NDA products.

FDA explained that traditionally FDA sees a placement in the b(4) Fenwal's approach is unique and data is required to review this, especially in a worst case scenario and for reproducibility. Fenwal stated that they provided this data 30-35 years from Baxter and Fenwal. Fenwal explained that the in these types of vessels; the product is on b(4) Placing a probe in the b(4) would be irrelevant b/c Fenwal never has product b(4). They do place probes on the b(4) b(4) b(4)

FDA explained that they biggest concern outstanding is the lack of reproducibility data. FDA just needs additional information. This doesn't have to be consecutive; it can be split up over a couple of months (could be worst case scenario). Fenwal explained that their b(4) is their worst case scenario; using a b(4) product as opposed to 500mL; the b(4) probe is the worst case. They can also send in data from empty chambers even for other appropriate cycles (similar temperatures). Will point FDA to any applicable NDAs - 811104/070 - this data was reviewed; also in the response referenced b(4) b(4) - this talks about b(4) probing techniques.