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: 15-OCT-2009

Document Date: 15-OCT-2009

Correspondence Purpose(s): Conversation record

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

FDA Participant(s): Destry Sullivan, OCBQ APPROVED
Heather Erdman, OBRR
Randa Melhem, OCBQ
Jennifer Schmidt, OCBQ

Summary: Sterility T-con

Comments: Fenwal and FDA discussed the validation of vessel b(4)
We (FDA) pointed out that during the qualification of the vessel as well as the b(4) studies performed under protocol 17913 , and 29791, there is an area of the b(4) (no BIs or TCs).
Fenwal's response is that they use a software program to determine the b(4) distribution of the BIs and TCs. They added that the b(4) approach will cover all the locations the life-time of the process. They acknowledged that the area of the b(4) , but that it will be eventually in future runs.
We reiterated that validation has to be performed at the b(4) of the process to give us assurance that all the locations meet the acceptance criteria.
Fenwal stated that they have been using this b(4) approach for over 30 years, and have been approved in several NDAs.
We told them that the data they provided is good but insufficient as it does not address all the areas of the Load.

Fenwal stated that they have a lot of retrospective data (for worst case amicus validation) which cover the b(4) and that they will provide it to us. We asked that the data provided should cover sterilization loads/cycles (temperature and time) comparable to the InterSol loads/cycles.

I (FDA) then asked about clarification regarding the designation of the positions for the probes (BIs and TCs) in the qualification studies: Mapping of b(4) locations and b(4) locations (example: b(4) and b(4)) as compared to the designation of the probes in the validation studies for vessel b(4) performed per protocols 17913 and 29791 (example: b(4)).
I explained that Fenwal has stated that for each b(4) there are b(4) b(4) . So the location of a probe placed at the b(4) is are b(4) , and that placed at

b(4) yet for the qualification studies Fenwal has designations b(4) b(4) referring to b(4) which contradicts their design of b(4) Fenwal stated that they need to look at the data to explain this discrepancy.
Fenwal asked that I send an email to describe the discrepancy, and they will respond today.

In addition I asked for a date to provide the information and they said they don't think it will take long, but they will provide the information by email today.

Action Items:
Fenwal will send retrospective data of amicus sterilization validation data (comparable cycle to InterSol) to cover the b(4) and to assure FDA that their sterilization process is valid.
FDA (Randa) will send an email to Fenwal to highlight the discrepancy of probe designation between the qualification and validation runs.
Fenwal will respond to FDA today to clear up the discrepancy and to inform us when the retrospective validation information will be provided.

Note: FDA participants - Randa, Destry, Jennifer
Fenwal participants - Cheryl Roscher, Ariel Gonzales, Brian McMullen, Stephan (sterility assurance)