Correspondence Detail Report

16-NOV-2009

CBER 510(k), PMA, and PMS Submissions

Submission ID BN080041
Supplement ID: 0
Submission Type NDA
Status: Response Review
Applicant Firm: Fenwal Inc
Product: AAA unidentifiable product

Date Rec. in CBER: 04-AUG-2008
Document Date 31-JUL-2008
Due Date: 12-DEC-2009
Responsible Organization: DBA
DCC Login ID: 446481

Originator: FDA

Correspondence DCC Login ID:

Correspondence Type: Telecon

Due Date Changed: N

CBER Received Date: 07-OCT-2009

Document Date: 07-OCT-2009

Correspondence Purpose(s): Information request

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

FDA Participant(s): Heather Erdman, OBRR
Randa Melham, OCBQ
Jennifer Schmidt, OCBQ

Summary: Container closure

Comments: CBER called to request for Fenwal's method for container closure/ leak test: want to know the protocol for testing this and how Fenwal determines if there is a leak (acceptance criteria). CBER also requested for a summary.

Fenwal stated that they would need to verify the method and would be able to provide the protocol/method and summary on Thursday 08Oct09. Fenwal believes that it is a b(4) b(4)

CBER referred to an earlier telecon that covered the mapping of the sterilization chamber, where CBER was asking reproducibility and worst case scenarios. CBER relayed that they thought there was a request for retrospective studies. Fenwal replied that they thought they could be done retrospectively or prospectively; they chose to do the prospective study only.

Fenwal called back to seek clarification regarding the leak testing. Fenwal cited procedural steps in the NDA: Sterilization section 4.2.6.5, page 68-69/317, of volume 1. CBER acknowledged this section and stated that they needed further information: e.g. acceptance criteria – process for determination of a leak; positive and negative controls; how small of a hole can be detected; etc.