

Davidson, Mark

From: Vatsan, Ramjay
Sent: Thursday, July 16, 2015 4:40 PM
To: Sugrue-Richards, Kathy (ksugrue@amgen.com)
Cc: Davidson, Mark
Subject: CMC Information Request

Dear Kathy,

This is an Information Request:

Please clarify the sterility test method used for talimogene laherparepvec Drug Product:

The tables in the BLA for Drug Product Specifications (3.2.P.5.1: Table 1 10⁶ and 10⁸ PFU/mL doses) list the sterility testing method as (b) (4) method while the validated method is a (b) (4) method (b) (4). Please clarify which method is your test method.

Please feel free to contact me directly if you need clarification on this question. Would appreciate a quick response.

Thank you,
Ramjay

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