From:	Riggins, Cindy
To:	Giordano, Erica; Patel, Manisha
Cc:	Ahmed, Narin
Subject:	RE: BL 125646 - Vector Final Container Information Request
Date:	Friday, March 24, 2017 9:59:26 AM
Attachments:	7008911_ANSW_MC_840_7.pdf DMF 11820_LoA_(b) (4)_21-Mar-2017.pdf DMF 012456_LoA_(b) (4)_20-Mar-2017.pdf DMF 016769_LoA_(b) (4)_20-Mar-2017.pdf TRPT-16-026 L&E Risk Assessment for the Adherent CTL019 VS & VP.PDF
Sensitivity:	Confidential

Dear Erica,

Attached are the responses to the Vector Final Container information request received on March 15, 2017. There are a total of 5 documents: one ANSW document and 4 appendices. We will follow up with a BLA amendment through the gateway of these documents.

Take care,

Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Wednesday, March 15, 2017 9:01 AM
To: Patel, Manisha
Cc: Riggins, Cindy; Ahmed, Narin
Subject: BL 125646 - Vector Final Container Information Request
Sensitivity: Confidential

Good morning,

For the vector product container closure system as described in section 3.2.S.6 (vector), please address the following and provide a response by noon on March 24, 2017:

Please provide detailed information (such as compatibility, toxicity and biological tests) regarding the components of the vector DP primary container closure system (the (b) (4) . This information may be provided by cross-reference to drug master files, if appropriate.

Section 3.2.S.6.2.1.1 (vector, container closure system) states that the vector final container is a (b) (4) , but 3.2.S.2.5.7 (vector, extractable and leachable assessment) states that the vector final container is a(b) (4) Please explain this discrepancy, and please submit the extractable and leachable assessment that is summarized in 3.2.S.2.5.7.

Please confirm that the (b) (4) used for the (b) (4) stability study is intended for use as final vector product storage. If not (as per discrepancy above), please provide justification for not repeating the CCI study.

Please provide correlation of the container closure integrity study with media to the vector product.

Please provide a detailed summary of the (b) (4) method validation which should include information on (b) (4) stability in the presence of media, method sensitivity and scientific rationale for a (b) (4)

Please consider adding CCIT at product expiry (b) (4) stability test point) as part of the stability program for the vector product.

Please confirm receipt of this request.

Thank you,

Erica Giordano
Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@fda.hhs.gov