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To: jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Comments/Feedback on Labels
Date: Tuesday, November 21, 2017 4:48:36 PM
Attachments:
(File Attachment comment)
image001.png

Hi Jim:

We had the following feedback/comments regarding the mock labels submitted to us:

Product and diluent vials labels are partial labels, have all required elements and additional info. No comments.

Comments on Pouch Label:

Statement "For Rx only" under the NDC should read "Rx only" (delete "for").
Delete "for subretinal injection" on the line between proper and trade names.
This appears elsewhere on label.
Delete "For Rx only" on the 4th line of text. Does not need to appear twice on the label.

Move storage info up to 3rd line.
Revise ROA statement to shorten, and remove bold font. Refer to the PI for instructions, use bold font because this is of high importance.
Suggested revised pouch label:

NDC 71394-415-01

Rx only
voretigene neparvovec-rzyl
LUXTURNATM

5 x 10¹² vector genomes/mL. No US standard of potency.
One (1) single-dose vial of voretigene neparvovec-rzyl, 0.5 mL per vial
Two (2) vials of Diluent for voretigene neparvovec-rzyl, 1.7 mL per vial
Store at = -65°C. Dilute before use. Discard unused portion.
For administration by subretinal injection

See package insert for full prescribing information and instructions for dosage and administration

Comments on Carton Label:

Apply same revisions as for pouch label.

Please note the "Store at -65 C" should be "Store at = -65°C".

(Unsigned signature field (Click to sign)) Signature field is unsigned

Thanks,

Please acknowledge receipt of this email.

Nevitt

Nevitt Morris

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