

From: Morris, Nevitt  
To: jim.wang@sparktx.com  
Cc: Morris, Nevitt  
Subject: BLA 125610 Spark Information Request 10.26.17 Labels  
Date: Thursday, October 26, 2017 10:42:34 AM  
Attachments:  
(File Attachment comment)  
image001.png

Hi Jim:

BLA 125610

Please acknowledge this email Information Request and respond by next week, November 2, 2017.

Please contact us for any additional questions.

1. Please be reminded that an FDA acceptable suffix must be added to the proper name voretigene neparvovec on the labels. Please refer to FDA letter regarding potential proper name suffixes sent you on October 25, 2017. Please comment on the acceptability of these suffixes.

2. Regarding your proposed carton label and pouch label, the prominence of the tradename is larger than the proper name. Therefore the labels do not meet the required regulations. The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the trademark and trade name. In addition, the color selection is very light and may present a problem. The contrast in color value between the proper name and the background shall be at least as great as the color value between the trademark and trade name and the background.

Please see 21CFR. 610.62 Proper name; package label; legible type.

(b) Prominence. The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the trademark and trade name. The contrast in color value between the proper name and the background shall be at least as great as the color value between the trademark and trade name and the background. Typography, layout, contrast, and other printing features shall not be used in a manner that will affect adversely the prominence of the proper name.

(c)  
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Thanks

Nevitt

Nevitt Morris

Nevitt  
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