

From: Khurana, Taruna
Sent: Tuesday, January 24, 2017 4:15 PM
To: 'Margaretten, Nadine'
Cc: Steele, Matthew; Sweeney, Colleen
Subject: Carton and container labels: BLA 125592 MK-8237

Dear Nadine,

Please revise the carton and container labels to include the following:

1. As per [21 CFR 610.62 (b)] the point size for the proper name on the carton labels should be at least as prominent as the trade name. There still appears to be a prominence issue due to the use of different fonts.
2. Please consider using Grastek Carton label as an example.

Let me know if you have any questions.

Thank you
Taruna

Taruna Khurana, PhD

Biologist (Regulatory)

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
Taruna.khurana@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

From: Margaretten, Nadine [mailto:nadine_margaretten@merck.com]
Sent: Monday, January 23, 2017 1:24 PM
To: Sweeney, Colleen
Cc: Khurana, Taruna; Steele, Matthew
Subject: Response to FDA comments, carton and container labels: BLA 125592 MK-8237

Dear Colleen,

We have made the following changes in the carton labeling to address the FDA comments regarding prominence :

- Changed the font color of the proper name to increase its prominence
- Decreased the font size of the Trademark to decrease its prominence

The font size/height of the proper name is 15 pt.

The font size/height of the Trademark is 11.3 pt.

Please can you forward the attachment to the FDA reviewer for the carton labeling? The attachment shows the proposed changes and the previous version for ease of the reviewer. We would appreciate quick feedback before we prepare the label submission with the carton labeling changes.

Thanks and best regards,
Nadine

From: Sweeney, Colleen [<mailto:Colleen.Sweeney@fda.hhs.gov>]

Sent: Wednesday, January 18, 2017 11:55 AM

To: Margaretten, Nadine

Cc: Steele, Matthew; Khurana, Taruna

Subject: RE: carton and container labels

Importance: High

Dear Dr. Margaretten:

Please revise the carton and container labels to include the following:

1. As per [21 CFR 610.62 (b)] the point size for the proper name on the carton labels should be at least as prominent as the trade name.
2. The lateral barcodes are missing from the carton labels. Please revise to conform with [21 CFR 610.67].
3. Please ensure that all detachable labels have only the following information: NDC, Proprietary Name, Lot and Expiry date.
4. Please confirm whether you intend to print the lot and expiry dates onto the labels as indicated.

Please send these revisions as an amendment to your BLA.

Thank you.

Colleen Sweeney R.N., M.S.

Captain, USPHS

Division of Vaccines & Related Product Applications

Office of Vaccines Research & Review

Center for Biologics Evaluation & Research

US Food & Drug Administration

10903 New Hampshire Ave

Silver Spring, MD 20993-0002.

Tel: +1 301 796 2640

E-Fax: +1 301 402 0004; Fax: +1 301 827 3075

E. Mail: colleen.sweeney@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you received this document in error, please immediately notify the sender by e-mail or phone.