



DEPARTMENT OF HEALTH & HUMAN SERVICES
FDA/CBER/OVRR/DVRPA

Memorandum

Date: August 16, 2016

From: Daphne D. Stewart, CSO
Regulatory Management Support Branch,
HFM-475, DVRPA/OVRR

Through: Laraine S. Henschel, Branch Chief, RMSB

To: BLA STN 125592/0 File

Subject Merck Sharp & Dohme Corp., BLA 125592/0
House Dust Mites Allergenic Extract
(Two Carton Labels, Two Detachable Labels and a SPL – ODACTRA®)

Summary

Merck Sharp & Dohme Corp. has submitted Biologic License Application of House Dust Mite (*D. farinae* and *D. pteronyssinus*) Allergenic Extract sublingual tablets for the treatment of Allergic Rhinitis/Rhino conjunctivitis. This BLA includes data to support use in Adults 19 through 65 years of age to the product labeling.

Labeling Review

Merck Sharp & Dohme Corp. have submitted two carton labels that consist of one that contains 30 sublingual tablets in 30 three 10 tablets blister cards and a sample – not for sale one that contains 5 tablets and 1 blister card and two blister cards that contain 10 spaces for tablets each and a SPL in this submission. I have the following comments:

Carton Label for Market (contains 30 sublingual tablets) that were relayed to the company in IR date June 8, 2016:

1. Per 21 CFR 610.62(b) Prominence; the proper name should be as prominent as the trade name.
2. The sponsor has mentioned "Lot & Expiry Area. Legends Printed Online." Does this mean that the sponsor will stamp both Lot & Expiry onto the labels at time of printing?
3. Also, the sponsor mentions "Upon Serialization, this encoding area will contain a 2D barcode, Serial Number, Expiry & Lot, GTIN will also be placed into this area"...the sponsor is required to submit the 2 DataMatrix Encoded Information for their 2D barcode.

Blister Label for Market:

1. All detachable labels are supposed to have NDC, Proprietary Name, Lot & Expiry.
2. The sponsor has mentioned "Lot & Expiry Area. Legends Printed Online." Does this mean the sponsor will stamp both Lot & Expiry onto the labels at time of printing?

SPL Label for Market:

This label appears satisfactory with the basic layout.

Sample Carton Label (contains 5 tablets):

1. Per 21 CFR 610.62(b) Prominence; the proper name should be as prominent as the trade name.
2. Per 21 CFR 610.62 (b) Prominence; back of the carton
USUAL DOSAGE: See package Insert
Merck & Co., Inc.

Sample Blister Label:

1. All detachable labels are supposed to have NDC, Proprietary Name, Lot & Expiry.
2. The sponsor has mentioned "Lot & Expiry Area. Legends Printed Online." Does this mean the sponsor will stamp both Lot & Expiry onto the labels at time of printing?

UPDATE:

Amendment One – August 11, 2016 submission that were relayed to the company in IR date August 16, 2016:

The labels appear to have the same issues as when I originally reviewed them on June 2, 2016 & August 16, 2016.

Sample Carton 5 tablets: (unable to locate regs for sample labels)

Blister Label for Market: (Detachable Labels)

The label is missing the actual NDC, Barcode, Lot & Exp

Carton for Market (30 sublingual tablets):

1. Per 21 CFR 610.62(b) Prominence; the proper name should be as prominent as the trade name.
2. The label is missing the actual Lateral Barcode.

UPDATE:

Amendment Two – January 17, 2017 submission that were relayed to the company in IR date January 13, 2017:

These labels continue to have the same issues that were submitted to you last year that need to be told to the sponsor. These labels need to be revised and resubmitted for review:

1. Per 21 CFR 610.62 (b) Prominence; the point size for the proper name on the carton labels should be at least as prominent as the trade name.
2. Per 21 CFR 610.67 Bar code requirements; the lateral barcodes are missing from the carton labels.
3. CBERs In-house Rules and Regulations for all Detachable Labels are to be streamlined to make sure the sponsors are now required to have the following on all their detachable labels; NDC, Proprietary Name, Lot and Expiry Only.
4. The sponsor should be asked about whether they intend to print the lot and expiry dates onto the labels as indicated...(need to double check to make sure)...

The sponsor has revised their trade name.

UPDATE:

Amendment Three – January 24, 2017 submission that were relayed to the company in IR date January 18, 2017:

It appears the sponsor is now in compliance with their labels.

Recommendations

These labels appear to be satisfactory and in compliance with 21 CFR 610.61 through 21 CFR 610.67 and 21 CFR 207.35.

Daphne D. Stewart