



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DATE	February 21, 2017
FROM	LCDR Matthew Steele, PhD
THROUGH	CAPT Jon Daugherty, PhD
STN Chair	125592/0 CAPT Colleen Sweeny
PRODUCT	House Dust Mite (<i>Dermatophagoides farinae</i> and <i>Dermatophagoides pteronyssinus</i>) Allergen Extract
APPLICANT	Merck Sharp & Dohme Corp.
SUMMARY	(b) (4) Labeling

I have reviewed the following materials as part of this review:

IR Sent 2/10/2017

Amendment(s) 67 received on 2/20/2017.

On February 10, 2017, CBER sent an information request to the Applicant requesting that they remove all references to (b) (4) from Medication Guide, Package Insert and Carton/container labels. This request was made because the proposed labeling implied that (b) (4). CBER requested that the references to (b) (4) be removed as the Applicant has not provided (b) (4) data to support this claim. Additionally, because the definition of (b) (4)

The Applicant agreed and submitted revised labeling on 2/20/2017. I reviewed this amendment and found it to be acceptable.