

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125592/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Merck Sharp & Dohme Corp. / Lic. # 0002
<b>Product</b>	House Dust Mites Allergenics Extract
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	04-APR-2016 04:12 PM
<b>Author</b>	SWEENEY, COLLEEN
<b>EDR</b>	No
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	No
<b>Communication Categories</b>	OT -
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	The sponsor contacted CBER to express concerns regarding the blister space constraints for MK-8237 and the requested Proper Name to include the full nomenclature for the HDM species. CBER asked if the sponsor had considered other options regarding how to
<b>FDA Participants</b>	Colleen Sweeney
<b>Applicant Participants</b>	Nadine Margaretten

**Telecon Body:** The sponsor contacted CBER to express concerns regarding the blister space constraints for MK-8237 and the requested Proper Name to include the full nomenclature for the two HDM species. CBER asked if the sponsor had considered other options regarding how to include the Mk-8237 proper name (with two full species names)

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on the blister card. CBER indicated that a minimum font size of 6 on the blisters was required.