

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

Telecon Date/Time	04-APR-2016 04:12 PM
Author	SWEENEY, COLLEEN
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	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
FDA Participants	Colleen Sweeney
Applicant Participants	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.