Medsafe is seeking comments on:

The changes proposed to CMN Form B.

• Change of category name from 'Bulk Active methods of manufacture' to 'Active Ingredient methods of manufacture -Grade 1'.	No issue. For consistency, it may also be advisable to change “Bulk active” to “active” throughout the document
• Addition of 'Grade 2' to the existing category 'Active ingredient method of manufacture.	No issue
• Additional criteria under 'Active Ingredient methods of manufacture - Grade 1' to explain that changes to the manufacturing processes used for the isolation and purification of drug substance from plasma should be notified under this category.	No issue
• Introduction of a Self-assessable change notification (SACN) category 'Active ingredient method of manufacture - Grade 3' (fee $360)	No issue
• Removal of the category 'Change in site of lyophilisation' (fee $1440). • Inclusion of a change in lyophilisation site under the category 'Finished product manufacturing site' (fee $2880)	No issue
• Removal of the category 'Revalidation of the lyophilisation process' (fee $1440).	No issue
• Introduction of the category 'Finished Product Testing site' (fee $1440).	The meaning of the second bullet point under FP testing site is unclear. This should be reworded for clearer definition or deleted.
• Revision of the criteria for 'Finished Product manufacturing process - Grade 3' (fee $720).	No issue
• Introduction of the SACN category 'Finished Product manufacturing process - Grade 4' (fee $360).	No issue
• Editorial changes to criteria listed under the various 'Test methods and specifications' categories/grades.	No issue
• Introduction of categories for 'Excipient specifications/test methods'.	No issue

• Introduction of the category 'Shelf life/Storage conditions - Reference standard used for potency/assay'	No issue

Additional Comments

Change in ownership	Mylan supports the deletion of a change in ownership as requiring a CMN
Security labelling declaration	Mylan supports the removal of the requirement to provide a physical sample of the security label
Container/closure/packaging grade 3	We would propose the fee for this category is $720 not $780 to align with other similar categories of CMN

Mylan also supports the comments made by the NZSMI with regard to changes proposed to Form A for these to also be applicable to Form B where there is overlap.

Mylan would request that feedback is also accepted on Form B once the revised Form A is published for consultation by Medsafe to ensure consistency between product types.

Please include additional pages if necessary.