Health Canada Santé Canada

Example: Summary of Post-Notice of Compliance Quality Changes

Reference: Post-Notice of Compliance (NOC) Changes: Quality Document (Effective date: 2016/10/14)

Post-NOC quality change according to guidance document (Please indicate the number for each change)	Description of change	Conditions to be fulfilled for this change and reporting category based on Health Canada guidance document	Explanation of how each condition is, or is not, fulfilled	Based on fulfilment of the conditions, what is the corresponding reporting category? (i.e. Supplement or Annual Notification)	Supporting data required	Location of required supporting data within submission or reason for omission
33. Replacement or addition of a primary container closure system for: **a)** sterile drug products	Change in the primary container closure system from blisters to bottles	None – This change is for a sterile product	N/A – No conditions to be met	Supplement	**1.** (1.3) Product Monograph [e.g., Where applicable, Title Page, Storage and Stability (Part I), Dosage Forms, Composition and Packaging (Part I)] and Inner and Outer Labels.	Module 1.3.1, Module 1.3.2
					2. (P.2) Data demonstrating the suitability of the container closure system (e.g., extractable/leachable testing, permeation testing, light transmission). For changes to functional packaging, data to demonstrate that the functioning of the new packaging is equivalent to that previously approved.	Module 2.2, Module 3.2.P.8.1, Module 3.2.P.8.3
					3. (P.3.5) For sterile products, process validation and/or evaluation studies. Evidence of process validation for sterilization processes for the container/closure.	Module 3.2.P.3.5
					4. (P.7) Information on the proposed container closure system (e.g., description, materials of construction of primary packaging components, specifications, including results of transportation studies, if appropriate).	Module 3.2.P.2, Module 3.2.P.7
					5. (P.8.1) Stability Summary and Conclusions, results of a minimum two (2) pilot scale, of three (3) months of accelerated (or intermediate as appropriate) and three (3) months of long term testing and, where applicable, results of photostability studies; (bracketing and matrixing for multiple strengths and packaging components could be applied, if scientifically justified).	Module 3.2.P.8.1
					6. (P.8.2) Updated post-approval stability protocol and stability commitment to place the first commercial scale batch of each strength of the proposed product into the long term stability programme (bracketing and matrixing for multiple strengths and packaging components could be applied, if scientifically justified).	Module 3.2.P.8.2

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Summary of Post-Notice of Compliance Quality Changes to [Brand Name] (S(A)NDS, Control No. xxxxxx)

Reference: Post-Notice of Compliance (NOC) Changes: Quality Document (Effective date: 2016/01/27)

Post-NOC quality change according to guidance document (Please indicate the number for each change)	Description of change	Conditions to be fulfilled for this change and reporting category based on Health Canada guidance document	Explanation of how each condition is, or is not, fulfilled	Based on fulfilment of the conditions, what is the corresponding reporting category? (i.e. Supplement or Annual Notification)	Supporting data required	Location of required supporting data within submission or reason for omission