2. POSTAPPROVAL STABILITY PROTOCOL AND STABILITY COMMITMENT [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

The postapproval stability protocol and stability commitment should be provided. These should include any un-completed registration batch stability studies, on-going marketed product stability commitments, etc. This commitment should be used to address the requirement to provide long-term data on three production scale batches.

Typically a commitment is also made to put a minimum of one batch per year per formulation and container closure system on stability. The stability protocol for postapproval studies is often more abbreviated than registration protocols.

A commitment to report to the FDA if the stability indicates any lot is outside of approved specifications including any decision to withdraw from the market based on the safety and efficacy issues associated with the deviation.

Reference ICH guidances Q1A and Q5C.