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Template for the Submission of Comments Draft Guidance Document/Issue Analysis Summary: Draft Pause the Clock proposal for pre-market submissions and applications

Comments submitted by

Full Name:
Company/Association Name: (if applicable):
Telephone number:
Address:
E-mail Address:
Date:

Your personal information on this first page will not be shared publicly.

Health Canada will summarize stakeholder comments received during this consultation in reports, such as a Summary of Comments and a What We Heard Report. Health Canada makes these reports publicly available.

Table with 3 columns: Section, Comment and Rationale, Proposed Revised Text. The table contains 18 empty rows for data entry.

What are your thoughts on the proposed triggers listed in our proposal? Please provide specific feedback on the proposed triggers.

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Can you think of a situation in the review process beyond those mentioned within the attached proposal where a trigger could be used?

When would it be valuable from industry's point of view to be able to pause the clock? Please describe under what circumstances this would occur.