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20 March 2019

Health Product Inspection and Licensing Division
Health Canada
13th Floor, Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture
Ottawa Ontario K1A 0K9
Canada

Reference: Guidelines for environmental control of drugs during storage and transportation (GUI-0069)

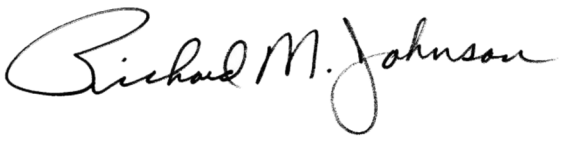
Dear Madam or Sir:

PDA appreciates the opportunity to comment on the revised Draft Guidelines for environmental control of drugs during storage and transportation (GUI-0069). In general, the use of plain language improves readability and comprehension. In Table 1, PDA offers suggestions that may help clarify the applicability of the guidelines in specific circumstances.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments have been prepared by a committee of volunteers with expertise in pharmaceutical and biopharmaceutical manufacturing on behalf of PDA's Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,



Richard Johnson
President and CEO

cc: Tina Morris, PDA; Ruth Miller, PDA

Table 1: Comments

Line Number	Page Number	Current Text	Proposed Revision or Comments	Rationale
	4	By definition, the term "drug" now includes Active Pharmaceutical Ingredients (APIs) used in drugs. This means APIs fall within the scope of this guidance as well.	PDA suggests that Health Canada may wish to give additional consideration of the specific needs for APIs, which may be significantly different from those of finished drug products. Health Canada also may consider including additional discussion of quality risk management and risk-based approaches to storage and transportation of APIs, consistent with ICH Q7 and the EC Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use.	In some cases, the language in this guidance may be more conservative than necessary for highly stable APIs, including those derived from mineral sources. While section 3 allows for "other ways of complying with the GMP regulations will be considered," additional discussion of such risk-based approaches would be appreciated and appropriate. Alternatively, Health Canada might consider detailing the ways in which the storage and transportation of APIs might differ from the storage and transportation of finished drug products.
	8	For more information, please refer to United States Pharmacopeia: General Chapters: <659> Packaging and Storage Requirements and <1079> Good Storage and Distribution Practices for Drug Products	We suggest omitting the reference to General Chapter <1079>, and referencing it only in Appendix B. Alternatively, Health Canada may wish to delay publication of the final version of this guidance document until USP publishes the revised version of General Chapter <1079>.	General Chapter <1079> is currently under revision by USP. On July 1, 2018, USP published a proposal to completely rewrite the chapter, and accepted comments on that proposal until September 30, 2018. The revised chapter is targeted to be published on June 1, 2019, and to become official on December 1, 2019. Because it is unclear what newly revised chapter will cover or say when finalized, Health Canada may wish to avoid referencing the chapter so explicitly in this guidance. Alternatively, Health Canada may wish to wait for the revised General Chapter to be published before finalizing this guidance.
	10-11	Section 4.2 Product Transportation, subsections 4, 5, 6, 7, 9.	PDA suggests that Health Canada carefully review this language for applicability to regulated parties, and potentially reframe the statements to reflect the role of the contracted	In scope, this guidance document applies to "all persons (individuals and companies) involved in the storage and transportation of drug products." In practice, the

			third party. For instance, consider noting that if a regulated party uses a contractor to store or transport drugs, the regulated party can contractually require the contractor to take the steps described to ensure product quality, including temperature mapping, temperature monitoring in transport, and assessment of vehicle suitability. Similarly, a manufacturer or distributor may use contractual language to ensure that the transportation contractor has contingency plans for unforeseen delays due to vehicle equipment malfunctions.	manufacturer or distributor may use a transportation contractor that conducts temperature mapping and/or temperature monitoring of its vehicles, but the manufacturer or distributor is unlikely to conduct temperature mapping of its contractors' vehicles as described in subsection 6. Similarly, it is the transportation contractor's role to develop policies and procedures to address vehicle equipment malfunctions, but the manufacturer or distributor can include language in a contract to address this. We believe these suggestions are consistent with Health Canada's intent and we appreciate the content in section 4.5, but suggest that clarifications to 4.2 could better describe the manufacturer/distributor's role when not physically transporting drugs.
10	11	Ensure loading and unloading activities preserve the quality of the drugs.	PDA understands the intent of this sentence but suggests that this general requirement is adequately covered by the other provisions of this section and can be omitted.	As written, the sentence somewhat vague. If Health Canada believes that this sentence is necessary in light of the other general statements in this section, we suggest revising it to be clearer in its interpretation.
	14	Excursions or damaged shipments must be investigated and any decision to accept or reject affected stock must be based on evidence.	PDA suggests revising this sentence to clarify that regulated parties may reject stock in the absence of definitive evidence. We suggest that the similar sentence on page 9 is more appropriate because it allows for technical justification: All excursions must be investigated and any decision to retain or dispose of affected stock must be based on evidence such as stability data, with technical justification.	While it is preferable to have definitive evidence to support any decision to reject stock following a temperature excursion, PDA suggests that regulated entities should be permitted to reject stock without definitive evidence. For instance, if existing stability data shows that the potential degradation following a given excursion may place the product on the borderline of acceptability, regulated parties should feel comfortable rejecting the affected stock.