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25, September 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 00D-1418
Comments to ICH; Draft Guidance on
Good Manufacturing Practice for Active Pharmaceutical Ingredients

Gentlepersons:

Agvar Chemicals Inc. is a supplier of active pharmaceutical ingredients and a founding member of the Generic Pharmaceutical Association (GPhA) On behalf of the Generic Pharmaceutical Association, we hereby submit the following comments to above subject draft guidance:

- The term "Significant structural fragment" in connection with the definition of "API Starting Material" should be more clearly defined and be part of the glossary.
- The glossary lacks a definition of the word "deviation", which is a very important term.
- With regard to point 4.22, the term "production area" is too broad. It should be more clearly specified as to the exact type of production area it refers to. For example, does it refer to production areas where a qualified HVAC system is in operation?
- Please be more specific as to what "GMP related computerized systems" mean.

Thank you for your review and consideration of the GPhA's comments to above subject draft guidance.

Cordially yours,

AGVAR CHEMICALS INC.

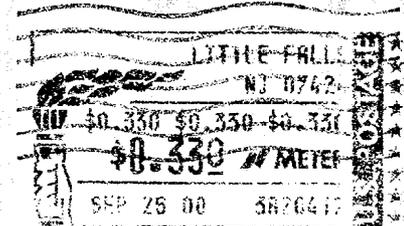
Margaret Hsiao
Vice President

00D-1418

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