



## Abbott

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October 14, 2005

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

Re: Docket No. 05D-0324  
Draft Guidance, ICH M5: Data Elements for Drug Dictionaries

Abbott Laboratories (Abbott) offers the following comments on the draft Guidance, ICH M5: *Data Elements and Standards for Drug Dictionaries*, published in the Federal Register on September 6, 2005.

### **General Comments**

Abbott welcomes this guidance as it will ease the burden on industry compliance with different regional requirements. However, regulatory authorities should ensure that the data element terminology is consistent and that the rules can be applied globally in order to ensure that the interchange process is not complicated.

The text and explanations are complex and may give rise to different interpretations. An attachment, with a representative set of examples and completed forms, should be appended in order to facilitate comprehension and training in the new procedures.

### **Introduction**

The terms “medicinal product” and “pharmaceutical product” may not have the same meaning worldwide. These terms should be defined at the beginning of the document.

### **Data Elements**

The data elements presented do not take into account products with co-licensing agreements in different territories. There would not be one and only one Marketing Authorization Holder unless only the innovator is listed.

Docket No. 05D-0324

Draft Guidance, ICH M5: Data Elements and Standards for Drug Dictionaries

Should you have any questions, please contact Ms. Lauren Hetrick, Senior Director,  
Regulatory Intelligence/FDA Liaison Office at (301) 255-0080.

Sincerely,

A handwritten signature in black ink that reads "D. L. Sporn". The signature is written in a cursive style with a large, looped initial "D".

Douglas L. Sporn  
Divisional Vice President