Health Canada Santé Canada

May 18, 2004

NOTICE

Our file number: 04-110130-760

Draft Comprehensive Summary: Bioequivalence (CS-BE)

A draft version of this Health Canada (HC) template is now available and will immediately supersede the Bioequivalence Studies module (i.e., Bioequivalence Studies: Comprehensive Summary) of the Preclinical and Clinical Evaluation Report Template (PCERT). This draft document is meant to assist applicants in the preparation of drug submissions that include pivotal comparative bioavailability studies, and in particular those submissions in the Common Technical Document (CTD) format developed by the *International Conference on Harmonization* (ICH). Comments and suggestions received on the draft version of CS-BE will be reviewed and considered in the finalization of this document.

Sponsors are encouraged to complete the CS-BE which is a summary of the conduct and analysis of comparative bioavailability (including bioequivalence) studies submitted in support of an application. This summary helps to ensure a consistent and timely evaluation process and provides sponsors additional guidance with respect to our expectations of technical requirements.

In addition, the draft CS-BE:

- removes unnecessary formatting;
- removes the requirement for 15% random replicate samples (as outlined in the Notice to Industry dated June 25, 2003, as well as the Notice to Industry dated September 24, 2003); and
- addresses concerns over proprietary software specifications. These templates are now available in both Corel® WordPerfect and Microsoft® Word to assist sponsors in their use. Please note: Sponsors are requested to submit the original template file only in Microsoft® Word 2000 or later, or in Corel® WordPerfect 6, 7, 8, 9, or 10. Sponsors must use the appropriate template for the word processing format of their choice (i.e., Word template for Word submissions and WordPerfect template for WordPerfect submissions).

Comments regarding the draft CS-BE should be submitted no later than July 25, 2004 and should be directed to:

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