

Stakeholder Feedback on

DRAFT GUIDANCE DOCUMENT

Conduct and Analysis of Comparative Bioavailability Studies

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Comparative Bioavailability Standards: Formulations Used for Systemic Effects

Comments submitted by: International Pharmaceutical Federation (FIP), special interest group for biopharmaceutical classifications system (BCS) and biowaivers
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Date: 26 March 2010

Comment:

The proposed document does not allow waiving of *in vivo* bioequivalence studies other than dose-proportionality and IVIVC.

However, we strongly suggest to include the possibility of waiving of *in vivo* bioequivalence studies for IR BCS Class I and BCS Class III drug substances, under the restrictions and conditions described in Appendix III of the recently adopted EMA Guideline on the investigation of BE, adopted January 2010, document CPMP/QWP/EWP/1401/98 Rev. 1.

Please, consider:

1.

Accepting waivers of *in vivo* BE studies for IR BCS Class I and BCS Class III drug substances under these restrictions and conditions would harmonize the Canadian regulations with the European regulations and also the WHO recommendations. In addition, it is expected that in the near future the FDA will apply the same regulations. Global harmonization is of interest of all stakeholders.

2.

Up to now, not one incorrect decision have been reported of waivers of *in vivo* BE studies for IR BCS Class I and BCS Class III drug substances under these restrictions and conditions, indicating its the conservative nature.