Reviewer's report

Title: The Canadian natural health products (NHP) regulations: Industry perceptions and compliance factors

Version: 2 Date: 7 March 2006

Reviewer: Mark Miller

Reviewer's report:

General
An interesting commentary on the Canadian approach. It serves as a potential guide for successes and failures for other governmental agencies.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1) The authors have not provided a list of abbreviations which given the vernacular would be invaluable.
2) Details of the format of safety studies that must be provided will be helpful. For example are these according to international standards (OECD), are they for the components or the final product as manufactured?
3) As I understand the backlog for review of submissions is substantial (years) and this has an impact. Additional comments on the length of the current backlog would help Non-Canadians appreciate the current situation.
4) There needs to be clarity as to the specific date (June 30, 2004) referred to. What if there is a new entrant that is after that date? Are the rules or regulations different? Is this a grandfather clause?

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
1) Comments on the expected costs per SKU to comply would be valuable as it relates to the impact on SME’s and new entrants.
2) Commentary to the latest EU changes with different standards for local (EU) vs foreign entrants is worthwhile discussing. This is also linked to the issues of innovation and barriers to market entry.
3) A comment about whether these regulations will help Canadian companies globalise its sales may be considered (meet the regulations of other countries or not).

Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field
Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

"I declare that I have no competing interests"