December 19, 2006

NOTICE

Our file number: 06-129002-483

Re: Category IV / Labelling Standards Submission Application Process Review

Category IV Monographs and Labelling Standards were introduced by the Therapeutic Products Programme in 1995 to facilitate the drug submission application process for those non-prescription products considered to be low risk. This was accomplished by the implementation of an administrative premarket review comprising verification of documentation necessary to support market authorization; no further review of products labels was conducted. Since the inception of this administrative process, it has become increasingly evident that most submission applications fail to meet the basic requirements of the monograph or label standard, despite signed attestations claiming compliance. In 2004, a more detailed premarket evaluation of the labelling of products submitted under the Category IV and Labelling Standards system was undertaken in an attempt to enhance compliance.

After a two year period of ongoing and resource- intensive clarification with sponsors on individual submissions, continued noncompliance and more limited resources necessitates reversion to the original intent of the *Guidance to Industry: Management of Drug Submissions*. Consequently, effective January 15, 2007, the Therapeutic Product Directorate will undertake premarket compliance activities for those Category IV Monograph or Labelling Standard submissions which do not meet the basic requirements of the monographs or label standards. In such cases, a Rejection Letter will be issued identifying which requirements were not met. Please note that submitted labels that clearly do not meet the criteria of C.01.004 of the *Food and Drug Regulations* may also be rejected. Please note that the fees submitted with these submissions will be retained, as per the *Guidance Document on Cost Recovery Submission Evaluation Fees* which states "Where there is no distinction between screening and review (eg. Category IV products) if submissions are rejected the full fee will be retained". The sponsor will be invited to either refile as a DINA or to revise the submission with respect to the noted monograph deficiencies and refile as a DINF.

The following are examples of the most frequent areas of noncompliance which may result in the issuance of a Rejection Letter:

Areas of Deficiency for Category IV Monograph/Labelling Standard Submissions

1. inadequate or revised directions for use
2. inadequate or revised dosage directions
3. inadequate or revised warning statements
4. incorrect monograph/standard used for attestation

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5. incorrect or additional indication
6. increased efficacy claims; claiming unproven therapeutic advantages
7. unacceptable active ingredient
8. unacceptable active ingredient concentration
9. unacceptable combination of active ingredients
10. unacceptable dosage forms

Further, please note that Category IV Monograph or Labelling Standard submissions which contain ingredients sourced from animal tissue obtained from countries which fall outside of the acceptable geographical regions will be subject to a review outside of the monograph and additional fees will apply.

This Notice replaces the policy "*Review of labelling information submitted with DIN applications*" dated July 2, 1991.

Should you have any questions or comments regarding the content of the guidance, please contact:

Bureau Gastroenterology, Infection and Viral Diseases
Therapeutic Products Directorate
Health Canada
A.L. 0202B1
101 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9

Phone: (613) 941-3207
Fax: (613) 941-1183
E-Mail: bgivd_enquiries@hc-sc.gc.ca