PHARMACY AND POISONS BOARD HONG KONG

香港藥劑業及毒藥管理局

Your Ref.: 貴處檔號

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C/O Drug Office

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公共衛 生 檢 測中心三樓

To: Certificate holders of registered pharmaceutical products

Dear Sirs / Madams,

Registered Pharmaceutical Products containing Methyl Salicylate for Topical Administration

On 17 February 2014, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Pharmacy and Poisons Board reviewed and discussed the safety related to methyl salicylate (e.g. Reye's syndrome, proper usage), and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing methyl salicylate for topical administration should include the following new safety information or similar meanings:

1. 兒童使用本品前,應諮詢醫生意見。

Consult or seek advice from a doctor before the use of this product by children.

2. 使用時避免觸及眼睛及黏膜。

Avoid contacts with eyes and mucous membranes when in use.

3. 患有感冒、水痘或發熱病的兒童避免使用含有水楊酸甲酯的產品。

Avoid to use products containing methyl salicylate in children who have a flu, chickenpox or fever.

4. 如對水楊酸有過敏反應者,使用本品前請諮詢醫生意見。

People who are allergic to salicylic acid should consult a doctor before using this product.

- 2. You are required to review, and revise if necessary, the sales pack labels and/or package inserts of the concerned products registered by your company to comply with the above requirements.
- 3. Please submit the revised sales pack label(s) and/or package insert(s) within 2 months from the date of this letter for approval. Otherwise, the Committee may consider to de-register or not to renew the registration of the products that do not comply with the above requirements.

Yours faithfully,

(Clive CHAN)

Secretary

Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

c.c. 7-15/3, Product Files CC/SYM