

To whom it may concern:

Regarding extended indication for selective histamine H<sub>1</sub> receptor antagonist/anti-allergic agent Talion<sup>®</sup> Tablets 5 and Talion<sup>®</sup> Tablets 10 in treating pruritus/itching accompanying urticaria and other skin diseases

Tanabe Seiyaku Co., Ltd. (President: Toshio Tanaka) received approval as of January 22, 2002 for Talion<sup>®</sup> Tablets 5 and Talion<sup>®</sup> Tablets 10, regarding extended indication in treating “pruritus/itching accompanying urticaria and other skin diseases (eczema/dermatitis, prurigo, and pruritus cutaneous).” Talion<sup>®</sup> is currently available for the treatment of allergic rhinitis.

Talion<sup>®</sup> Tablets 5 and Talion<sup>®</sup> Tablets 10, second-generation antihistamines jointly developed by Tanabe Seiyaku and Ube Industries, Ltd. (President: Kazumasa Tsunemi), were approved for the treatment of allergic rhinitis in July 2000 and launched in October in the same year. They quickly relieve three most common symptoms of allergic rhinitis, i.e., sneezing, nasal discharge, and nasal obstruction, and can now be prescribed to improve skin symptoms, as approval for this use has been granted. Pruritus/itching and wheals, symptoms of urticaria, are caused by histamine binding to histamine H<sub>1</sub> receptors in sensory nerves and blood vessels. Talion<sup>®</sup> suppresses these symptoms by blocking histamine access to these H<sub>1</sub> receptor sites. Since the drug does not readily enter the CNS, it less often causes drowsiness, an adverse side effect of antihistamines.

For the clinical trial of Talion<sup>®</sup> aimed at obtaining approval for the extended indication, we recruited patients with chronic urticaria from the public through advertisements for the first time. The study went smoothly. Urticaria symptoms are transient and recur repeatedly. Since the symptoms pruritus/itching and wheals can be assessed by patients themselves, for the first time in Japan in assessing these two symptoms we used patients’ subjective assessment severity scores (recorded in patients’ diaries) to augment physicians’ objective evaluations. Talion<sup>®</sup> treatment effect was clinically assessed using this highly accurate system, and rapid improvement in target symptoms was demonstrated.

We are determined to continue helping patients with allergic rhinitis and with pruritus/itching accompanying urticaria or other skin diseases, by providing Talion<sup>®</sup> Tablets 5 and Talion<sup>®</sup> Tablets 10 and by continuing to gather useful information that we will share with those in need.