

Premarket Notification for Semen Cúscutae in VI-28

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NEW DIETARY INGREDIENT NAME: SEMEN CUSCUTAE (Cuscuta
Chinensis Lam.; Cuscuta japonica
Choisy)

INTENDED USE: Semen Cuscutae is intended for use as a dietary ingredient in the dietary supplement product, VI-28. The dietary supplement product will contain 60 mg of Semen Cuscutae per capsule, for a dietary intake of up to maximum 120 mg per day.

PRESENT IN FOOD SUPPLY

Semen Cuscutae has likely been present in the United States food supply, most likely in staple crops including soybean, potato, and pumpkin²⁰. Specifically, Semen Cuscutae has been known to parasitize such staple crops. While being considered a parasite, it is a likely fact that during harvest, Semen Cuscutae was harvested along with the staple crop, and unknowingly utilized during the production of foods.

Further to its past use, Semen Cuscutae has frequently been known as a medicinal herb that is sold under a variety of names include "Dodder Seed Semen", "Cuscutae" and "Tu Si Zi"²¹.

HISTORY OF USE/SAFETY EVIDENCE FOR NEW DIETARY INGREDIENT:

The history of use of Semen Cuscutae can be established from a review of scientific literature. In one study, a dietary supplement, EquiguardTM, currently available in the United States, concluded that the ingredients of the dietary supplement were effective in prohibiting the effects of carcinoma²². Notably, EquiguardTM ingredients include Cuscuta Chinensis Lam. (Semen Cuscutae).

Evidence of the safety of the dietary ingredient is shown in the study performed on the dietary supplement VI-28. A summary of the study and a copy are attached herewith²³.

²⁰ NPAG DATA: Cuscuta Japonica (Japanese Dodder) 11/2001, pp. 5.

²¹ Id. at pp. 8.

²² Hsieh, T. et al. "Effects of herbal preparation Equiguard on hormone-responsive...", Intern. Jour. of Oncology 20: pp. 681-689 (2002).

²³The letter from Dr. Laurence S.L. Shek and Anti-ageing Study show the results of administration of VI-28.

Safety evidence for the use of Semen Cuscutae is stated in the American Herbal Products Associations Botanical Safety Handbook (BSK)²⁴. The BSK, in arranging herb ingredients, positions them in classes according to their safety. A list of the classes is attached herewith. *Cuscuta chinensis* Lam. is classified in Class 1, which refers to herbs which can be safely consumed when used appropriately.

²⁴ McGuffin, M et al. (ed.) "American Herbal Products Association's Botanical Safety Handbook".