Premarket Notification for Cornu Cervi Pantotrichum in VI-28

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NEW DIETARY INGREDIENT NAME:	CORNU CERVI PANTOTRICHUM (Pilose Antler[6])

INTENDED USE: Cornu Cervi Pantotrichum is intended for use as a dietary ingredient in the dietary supplement product VI-28. The dietary supplement product will contain 75 mg of Cornu Cervi Pantotrichum per capsule, for a dietary intake of up to maximum 150 mg per day.

HISTORY OF USE/SAFETY EVIDENCE FOR NEW DIETARY INGREDIENT:

The history of use of Cornu Cervi Pantotrichum can be established via a review of literature. In China, the red deer species is raised for their young pilose antlers[7]. According to the literature, red deer, a member of the Cervus species, has been farmed to produce velvet antler teas, extracts, capsules and tablets for health related products[8]. Currently, many countries produce velvet antler including New Zealand (450 tons/year), China (400 tons/year), Russia (80 tons/year), United States (20 tons/year), and Canada (20 tons/year)[9]. Velvet antler supplements have been the subject of numerous studies[10].

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 herewith[11].

In one study, Senescence-Accelerated Mice were administered subchronic oral doses of hot-water extract of pilose antler (Rokujo)[12]. Doses were given orally for 8 successive days in amounts of 0, 100, or 200 mg/kg/d[13]. In a scientific review, researchers studied acute and sub-chronic toxicity of powdered deer velvet at dose levels of 2000 mg/kg for single oral treatment, and 500 mg/day orally for 90 days in rats[14]. It was reported that there were no

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[6] Monograph, "Cornu Cervi Pahtotrichum", www.healthlink.com.au/ant_lib/htm-data/htm-herb/bhp927.htm.
[7] "Young Pilose Antler- A Precious Crude Drug", pp. 43-45.
[8] Batchelder, H. "Velvet Antler: A Literature Review", www.natraflex.com/studies,/VA2.htm.
[9] Id. at pp. 1.
[10] Id., Antler extract was orally administered to rat and dog to determine plasma level of chondroitin sulfate (pp. 8-9), Antler extract was administered to rats to study level of monocytes (pp. 11), antler was administered to male athletes to determine effect (pp. 14).
[11] The letter from Dr. Laurence S.L. Shek and Anti-ageing Study show the results of administration of VI-28.
[12] Wang et al. "Effects of Repeated Administration of Deer Antler Extract on Biochemical Changes Related to Aging in Senescence-Accelerated Mice", Chem Pharm. Bull. 36, pp. 2587-2592.
[13] Id. at pp. 2589.
[14] Suttie, J. and Harris, S. "Clinical Properties of Deer Velvet",

pathological findings. Further, deer velvet powder was tested on reproduction and developmental toxicity, which was shown to have no effect on conception rates[15].

Bovine Spongiform Encephalopathy (BSE) and Cornu Cervi Pantotrichum

During a telephonic meeting held with the FDA on 20 April 2004 regarding the dietary ingredient Cornu Cervi Pantotrichum, concern was expressed for the ingredient being infected with BSE, a transmissible spongiform encephalopathy (TSE), and its transmission to users of the ingredient.

Firstly, it is important to note that BSE is not known to infect deer, rather Chronic Wasting Disease (CWD) is known to infect deer[16]. Second, in view of current studies, it is the Notifier's contention that use of Cornu Cervi Pantotrichum in VI-28 is reasonably safe.

CWD is known to be an infectious agent present in free-ranging deer and elk in Wyoming and Colorado. As for transmission to humans, current epidemiologic and laboratory investigations have concluded there is no strong evidence for a causal link between CWD and Creutzfeldt-Jakob disease (CJD- the form of TSE in humans)[17]. In developing such conclusion, the researchers reviewed several cases of humans who died of apparently rare neurological disorders. The patients did not appear to possess a common history with regards to exposure to deer or elk. Some patients apparently consumed venison, however it was not clear that the meat was infected with CWD. In some cases, the meat was from areas not known to be infected with CWD (Michigan)[18]. In addition, the report concluded that because there has not been an increase in the cases of CJD in Colorado and Wyoming (areas known to be infected with CWD), the risk of transmission to humans is low.

Further research has shown that a barrier at the molecular level likely limits the susceptibility of non-cervid species to CWD[19].

Cornu Cervi Pantotrichum as used in VI-28 is obtained from the People's Republic of China, an area not known to contain instances of CWD-infected deer. It is also believed the method of preparation of Cornu Cervi Pantotrichum likely addresses potential prion proteins.

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www.positivehealth.com/permit/Articles/Nutrition/sut54.htm.

[15] Id.

[16] "Commonly Asked Questions About BSE in Products Regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN)", U.S. Food and Drug Administration, January 14, 2004.

[17] Belay et al. "Chronic Wasting Disease and Potential Transmission to Humans", Emerging Infectious Diseases, Center for Disease Control and Prevention, Vol. 10, No. 6 (2004).

[18] Id. at pages 4-5

[19] Raymond et al., "Evidence of a molecular barrier limiting susceptibility at humans, cattle, and sheep to chronic wasting disease", The EMBO Journal, Vol. 19, No. 17 (2000).

Cornu Cervi Pantotrichum is boiled and dried, then ground into a power and encorporated into VI-28. The entire VI-28 mix is then dried at 80°C for 24 hours.

Based on the literature and in comparison to the intended use of Cornu Cervi Pantotrichum in VI-28, it is believed that Cornu Cervi Pantotrichum can reasonably be expected to be sate. Namely, the literature shows Cornu Cervi Pantotrichum administered at doses (2000mg/kg and 500 mg/day for 90 days) that are significantly higher than that of VI-28 (maximum 150 mg daily), with no ill effects. Further, through the method of preparing Cornu Cervi Pantotrichum, it is believed that prion proteins are likely eliminated.