WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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PHA Information Exchange System

ALERT

DIETARY SUPPLEMENTS CONTAINING L-TRYPTOPHAN

RECALLED IN THE UNITED STATES OF AMERICA

The Food and Drug Administration has issued a Press Release announcing the recall of products containing the amino acid compound, L-tryptophan, used in over-the-counter dietary supplements, because of the increasing number of cases of eosinophilia-myalgia syndrome reported in patients using them. The following is quoted from the Press Release:

"The Food and Drug Administration said last week that it will seek nationwide recall of all over-the-counter dietary supplements in which L-tryptophan, an amino acid, is the sole or major component of the product, because of the rising number of patients taking the product diagnosed as having eosinophilia-myalgia syndrome, a rare blood disorder.

"Consumers are urged to stop using the L-tryptophan supplements, which are widely available in health food stores as well as in such major retail outlets as supermarkets and drug stores.

"The FDA will request all manufacturers of the food supplement to recall these products. Each manufacturer would be expected to contact its clients (wholesalers, distributors and retailers) to remove the products from the marketplace.

"While the investigation continues, the FDA, the Centers for Disease Control and state health officials have now concluded that there is 'a strong, virtually unequivocal link between consumption of L-tryptophan tablets or capsules and the syndrome'. What has not been established by government scientists is the reason why ingesting L-tryptophan is associated with the syndrome. Most, but not all, of the affected patients have been individuals who were taking L-tryptophan tablets, caplets or capsules before becoming ill. The syndrome nearly always involves severe muscle and joint pain, swelling of the arms and legs, skin rash and possible fever. It is characterized by intense eosinophilia, a blood abnormality in which white blood cells increase to abnormally high levels.

"To date, CDC has received reports of 287 cases in 37 states plus the District of Columbia. According to CDC, there has been at least one death that is most likely due to consumption of L-tryptophan. Based on all available information, the FDA considers that the disease posed a 'moderate to severe and perhaps life-threatening hazard to certain individuals' and that some victims may suffer chronic after-effects in the future.

"The dietary supplement is sold under the name L-tryptophan as well as under a wide variety of other brand names in which L-tryptophan is the sole or major ingredient. FDA's warning applies only to those products. To date, none of the cases investigated appear to involve multi-ingredient food supplements, some of which may have L-tryptophan as a minor ingredient.

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"L-tryptophan is reportedly used by some individuals for sleeping difficulties, premenstrual syndrome, stress, depression and alcohol and drug abuse. The FDA has not approved L-tryptophan as a medicinal drug."

Reference: HHS News P89-49 dated 17 November 1989.

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