

DEPARTMENT OF HEALTH

FOOD AND DRUGS ACT

Food and Drug Regulations — *Amendment*

Interim Marketing Authorization

Formulated liquid diets are foods for special dietary use that are sold or represented as nutritionally complete diets and that have been specially processed or formulated to meet the particular requirements of a person in whom a physical or physiological condition exists as a result of a disease. The *Food and Drug Regulations* set out nutritional requirements for formulated liquid diets. These requirements include minimum levels for 18 vitamins and mineral nutrients and, in the case of vitamins A and D, maximum levels.

Health Canada has received a submission to exempt formulated liquid diets formulated specifically for patients with renal failure from the application of the minimum requirements of vitamins A and D and the mineral nutrients phosphorus and magnesium. The dietary management of vitamins A and D and the mineral nutrients phosphorus and magnesium must be individualized for patients with renal failure based on the specific condition of the patient. Optimal intake levels of these vitamins and mineral nutrients will vary depending on the age and body weight of the patient and the severity of the renal failure.

Health Canada has completed a safety assessment of the proposal to exempt formulated liquid diets for patients with renal failure from the application of the current minimum requirements for the nutrients named above. Evaluation of the available data supports the safety of the exemption of formulated liquid diets for patients with renal failure from the minimum levels for vitamins A and D and for the mineral nutrients phosphorus and magnesium. Patients with renal failure are under strict medical supervision which would ensure the safe use of such products. The *Food and Drug Regulations* prohibit the advertising of formulated liquid diets to the general public. Formulated liquid diets with lower levels of vitamins A and D and of the mineral nutrients phosphorus and magnesium than the currently permitted levels under the Regulations have been sold under Temporary Marketing Authorization Letters for a number of years with no reported adverse effects.

Health Canada therefore intends to recommend that section B.24.102 of the *Food and Drug Regulations* be amended to exempt liquid diets formulated specifically for patients with renal failure from the application of the minimum requirements of vitamins A and D and of the mineral nutrients phosphorus and magnesium to meet the specific dietary needs of these patients.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) is being issued to permit the immediate sale of liquid diets formulated specifically for patients with renal failure and exempted from the application of the minimum requirements of vitamins and mineral nutrients, as indicated above, while the regulatory process is undertaken to amend the Regulations formally.

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