**No. R. 493** **26 April 2002**

## FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT NO. 54 OF 1972)

## REGULATIONS RELATING TO THE LABELLING OF FOODS FOR SPECIAL MEDICAL PURPOSES

The Minister of Health intends, in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), to make the regulations in the Schedule.

Interested persons are invited to submit any comments on the proposed regulations or any representations they wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria 0001 (for the attention of the Director: Food Control), within three months of the date of publication of this notice.

SCHEDULE

**Definitions**

1. In these regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and in these regulations-

"Act" means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972); and

**Requirements**

2. Foods are for special medical purposes if they are for special dietary use and –
   (a) are specially processed and presented for the dietary management of patients;
   (b) are intended for the exclusive or partial feeding of patients -
      (i) with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein; or
      (ii) who have other special medically determined nutrient requirements,

   whose dietary management cannot be achieved by modification of the normal diet, other foods for special dietary use or by a combination of the two; and

(c) when used as the sole source of nutrients, the composition of these foods is such that they can provide the full range of known nutrients for normal people.

**Formulation, use and advertising**

3. The formulation of foods for special medical purposes must be based on generally recognised medical and nutritional principles.

4. Food for special medical purposes must have been demonstrated by results from scientific research or studies to be safe and effective in meeting the nutritional requirements of persons for whom they are intended.

5. The advertising of these products to the general public is prohibited.

**Labeling**

6. (1) Foods for special medical purposes shall in addition to these regulations be labelled in accordance with the Regulations Relating to the Labelling and Advertising of Foodstuffs made in terms of the Act.

(2) Notwithstanding subregulation (1), regulations [ ...*to be inserted once the labelling and advertising of foodstuffs regulations are finalised*...] of the Regulations Relating to the Labelling and Advertising of Foodstuffs do not apply to the labeling of foods for special medical purposes.

7. The labels, accompanying leaflets and advertisements of foods for special medical purposes must provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for its use.

8. The labelling of foods for special medical purposes must be as follows:

(a) the labelling must indicate the following nutritional information:

(i) the declaration of nutrient content in numerical form;
(ii) the energy value, expressed in kJ per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption;
(iii) the amounts of protein, carbohydrate and fat in the food, expressed in grams per 100 g or per 100 ml as sold, as well as per specified quantity of the food

suggested for consumption. Information on the amounts of essential and non-essential amino acids or essential fatty acids may be expressed similarly in metric units;

(iv) the amounts of vitamins and essential minerals, in metric units per 100 g or per 100 ml as sold as well as per specified quantity of the foods as suggested for consumption;

(v) where applicable, the quantity of nutrients per specified quantity of the food as suggested for consumption, in terms of percentages of the recommended daily allowances as described in Annex 3 of the Regulations Relating to the Labelling and Advertising of Foodstuffs;

(b) the labelling must also contain the following information:

(i) osmolality or osmolarity on acid-base balance where appropriate;

(ii) the number of servings or portions contained in the package;

(iii) the nature of the animal or plant protein hydrolysates;

(iv) where the essential characteristic of the foods involves a specific modification of the content or the nature of the proteins, fats or carbohydrates has been modified, the description of the modification and information on the amino acid, fatty acid or carbohydrate profile, where applicable;

(v) the statement, "USE UNDER MEDICAL SUPERVISION", shall prominently appear on the label in bold, capital letters not smaller than 3 mm in height in an area separated from other written, printed, or graphic information;

(vi) adequate directions for the preparation, including the requirement to add other ingredients, for the use of the food and for its storage and keeping after the container has been opened;

(vii) an additional prominent warning statement consisting of an explanatory statement in bold letters in an area separated from other written, printed or graphic information if the foods pose a health hazard when consumed by persons who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended;

(viii) a statement that the product is not to be used for parenteral administration;

(ix) a statement indicating whether the product is or is not intended as the sole source of nutrition;

(x) the statement "For the dietary management of... " , indicating specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective;

(xi) a statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, where applicable;

(xii) a statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful;

(xiii) if the product has been formulated for a specific age group, a statement to this effect;

(xiv) a statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification; and

(xv) feeding instructions, including the method of administration and serving size, where applicable.

**ME TSHABALALA-MSIMANG**

**MINISTER OF HEALTH**