



Federal Office for  
Consumer Protection and  
Food Safety

Federal Office for Consumer Protection and Food  
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YOUR REFERENCE  
YOUR MESSAGE OF

06. February 2014

REFERENCE NUMBER  
(Please specify in response)

BVL-101.11152.0.0018(2014)

DATE 20 February 2014

**Notification of a Food for Special Medical Purposes (balanced diets) according to § 4a  
para. 1 of the Ordinance on Dietetic Food (German DiätV)**  
Product "Mevalia Fusilli with container size 500g

Dear Sir/Madam,

I hereby confirm receipt of your notification according to § 4a Abs. 1 DiätV of 6 February 2014 for the product "Mevalia Fusilli" with the container size 500g. The present notification is a second notification.

As part of this notification procedure, I will only formally check the submitted documents for their completeness. It is being verified whether the information on the notification is complete and whether the notification falls under the conceptual requirements of one of the groups listed in Annex 8 DiätV. The BVL does not carry out any further examination of the content. For this purpose, the notification shall be forwarded to the regional authority responsible for food control.

The distributor is not exempt from the obligation to comply with food law regulations on his/her own responsibility.

In order to meet the general legal requirements for a dietetic food, the product must meet a special nutritional need of a consumer group according to section 1 paragraph 2 no. 1 DiätV. The second requirement is suitability for the stated intended use (Paragraph 1(2) No. 2 DiätV). In addition, the product must be clearly distinguishable from foods for general consumption, such as food supplements, fortified foods or other foods, due to its special composition or the special method of production.

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The specific legal requirement for balanced diets is the extended definition according to section 1 paragraph 4a DiätV. According to this definition, dietary foods for special medical purposes (balanced diets) are products that are processed or formulated in a special way and are intended for the dietary treatment of patients. They are intended for the exclusive or partial nutrition of patients with reduced or impaired ability to ingest, digest, absorb, metabolise or excrete ordinary foods or certain nutrients contained therein or their metabolites, or for the nutrition of patients with other medically related nutrient requirements for whose dietary management a modification of the normal diet, other foods for special nutrition or a combination of both is not sufficient. In addition, the special nutritional need must be medically related to nutrition.

According to Paragraph 3 of the DiätV, exceptions from the prohibition of disease-related advertising according to paragraph 12 of the German Food and Feed Code (LFGB) apply to balanced diets. However, in deviation from this, the disease-specific statements mentioned in Paragraph 3(2) of the DiätV are permissible for the indications listed therein. The advertising of other diseases for a balanced diet is not possible.

If the product is changed (e.g. product name, composition, etc.) a notification of change is required. I would also ask you to inform me if you should take the above product off the market (indicating the date).

The notification procedure of balanced diets is currently free of charge.

Kind regards,

On behalf

Dr. Evelyn Breitweg-Lehmann  
Referee