

### For Welsh Government Use Only

Date notification received:	<input type="text"/>
Date confirmation sent to manufacturer importer	<input type="text"/>
Date letter sent to Local Authority	<input type="text"/>



Llywodraeth Cymru  
Welsh Government

[www.cymru.gov.uk](http://www.cymru.gov.uk)

## Notification of Medical Foods

### Important Notes

1. Notification of medical foods is a statutory requirement under the Medical Food Regulations (Wales) 2000 (SI No. 1866 (W.125)).
2. Notification is required when a medical food is first placed on the market in Wales. Similar legislation applies in England, Scotland and Northern Ireland.
3. The term "medical food" means food coming within the classification of dietary foods for special medical purposes for which the compositional and labelling requirements are laid down in Commission Directive 1999/21/EC (as amended) on dietary foods for special medical purposes\*. Copies of this legislation can be obtained from:
  - The Office of Public Sector Information  
Tel No: 0870 600 5522  
Fax No: 0870 600 5533  
Website: [www.opsi.gov.uk](http://www.opsi.gov.uk)
  - Official Journal of the European Communities L91, 7/4/1999, p29; Corrigendum OJ L2, 5/1/2000, p79.
4. This form may be used as a means of notifying the Welsh Government when a medical food is placed on the market in the UK.  
  
The duty to notify falls on:
  - The manufacturer or importer
5. A **separate** form should be completed for **each** product. A copy of the product label must accompany each form.
6. If you have any queries about the completion of this form, please telephone or e-mail the Welsh Government at the address given at the end of this form.

### Contact Details

Health Improvement Division  
Welsh Government, Cathays Park  
Cardiff, CF10 3NQ  
Tel: 02920 825953  
Email: [Lifestyles@wales.gsi.gov.uk](mailto:Lifestyles@wales.gsi.gov.uk)

## Manufacturer/Importer details

It would be helpful if you could provide below your manufacturer/importer details.

Are you the: manufacturer **OR** importer (Tick ONE box only)

Company name:

Contact name:

Address (in full):

Telephone No: (including national dialling code)

Fax No: (including national dialling code)

E-mail:

Postcode:

If imported, in which country is the product manufactured?

Has this product been notified as a PNU food in other EU Member States? YES NO

If **YES**, please provide details of the recipient of the first notification in the European Union.

## Product details

Product name:

- (a) **Nutritionally complete food with standard nutrient formulation** which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended.
- (b) **Nutritionally complete food with nutrient-adapted formulation** specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended.
- (c) **Nutritionally incomplete food** with a standard formulation or nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as a sole source of nourishment

The foods referred to in categories (a) and (b) may also be used as a partial replacement or supplement to the patient's diet.

For which disease, disorder or medical conditions is this product intended?

Date this product is being put on the market

## Local Authority details

It would be helpful if you could provide below your Local Authority details below

Name and address of the local food enforcement authority for your company

Contact name:

Telephone No: (including national dialling code)

Fax No: (including national dialling code)

E-mail:

Postcode:

A model of the product label should be sent with this form to the Welsh Government at the address given on the front page.

Please tick this box to confirm you have done so:

Has the intended use of the product rendered it necessary to modify the compositional requirements from those laid down in Directive 1999/21/EC?    YES                      NO

If YES, please attach supplementary information relevant to this notification.

Signature:

Full name:

Date:

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Email: [Lifestyles@wales.gsi.gov.uk](mailto:Lifestyles@wales.gsi.gov.uk)