

Notification of Medical Foods

Important Notes

1. Notification of medical foods is a statutory requirement under the Food for Special Medical Purposes (Scotland) Regulations 2000 (SSI 2000 No. 130)
 2. Notification is required when a medical food is first placed on the market in Scotland. Similar legislation applies in England, Wales 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
- * [link to Commission Directive 1999/21/EC](#)

For use by Food Standards Scotland only

Date notification received	
Date confirmation sent to manufacturer / importer	
Date Local Authority notified	

4. This form may be used as a means of notifying Food Standards Scotland when a medical food is placed on the market in Scotland.
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, fax or e-mail the Department of Health at the address given at the end of this form.

■ Manufacturer / Importer details

Tick ONE box only

- Are you:
- the manufacturer
 - or
 - the importer

Name and full postal address

Postcode

Contact name

Telephone number (including national dialling code)

Fax number (including national dialling code)

E-mail

If imported, in which country is the product manufactured?

■ Products details

Product name

Product description

Product category

Tick ONE box only

- (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 your Local Authority details below.

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

Postcode

Contact name

Telephone number (including national dialling code)

Fax number (including national dialling code)

E-mail

A model of the product label should be sent with this form to Food Standards Scotland at the address given on this 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

Food Standards Scotland,
Medical Foods Notification,
Regulatory Policy Branch
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Aberdeen
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