APPENDIX 7

THE MECHANISM FOR ENSURING THAT PATIENTS ARE PROTECTED WHEN PRODUCTS ARE CLASSIFIED AS "BORDERLINE SUBSTANCES"

An active working relationship exists between the following organisations

- Medicines and Healthcare products Regulatory Agency (MHRA)
- Advisory Committee on Borderline Substances (ACBS)
- Nutrition Legislation Team, Healthy Behaviours, Population Health Directorate, Department of Health

The purpose of all three groups is to ensure that products are appropriately classified and that patient safety is ensured (as far as is practicable) in terms of product safety and subsequent administration. The table below describes the principal components of the process.

Component	Agency	Purpose
Determination that the product is not a medicine	MHRA	To confirm that the product is not a medicinal product and therefore does not require to be licensed under the terms of: - The Consolidated Pharmaceutical Directive (EU/2001/83) relating to medicinal products for human use - The Medicines for Human Use (Marketing Authorisations etc) Regulations 1994 as amended The MHRA will only state whether or not the product is a medicinal product. Any further definition has to be determined by other authorities.

Confirmation that, although the product is not a medicine, it has specific attributes justifying its prescription in the community as part of the clinical management of a specific condition	ACBS	To confirm that the product is effective and efficacious in the management of specific clinical conditions and to ensure that the prescription is as safe as possible. Notes: The ACBS is, by definition, advisory rather than regulatory. However, decisions made by the ACBS on justifiable requirements in the interests of patient safety, e.g. peptide chain lengths and / or acceptability of remnants of any enzymes, which may be unacceptable to particular cultures, are likely to be upheld by the DH In considering whether a particular substance, preparation or item should be approved, the ACBS will have regard to the need to ensure that substances, preparations or items which have a therapeutic use in the management of disease in the community can be provided as economically as possible under the NHS.
Products that are deemed to be FSMP must be notified to the competent authority, i.e. Nutrition Legislation Team, Healthy Behaviours, Population Health Directorate, Department of Health	Population Health Directorate	To receive the notification of a food for special medical purposes as defined in Commission Directive 1999/21/EC. Note: Trading Standards Officers are responsible for enforcing food law. They are employed by local authorities who are autonomous and they work in close conjunction with the Population Health Directorate.