TYPE OF NUTRITIONAL APPLICATION

TYPE 1

NEW FORMULATIONS WHICH THE APPLICANT PERCEIVES TO HAVE WELL CHARACTERISED AND SUBSTANTIATED ADVANTAGES IN TERMS OF NUTRITIONAL COMPOSITION AND PATIENT TOLERANCE / ACCEPTABILITY

These applications will require a full application. Please refer to the Information Notes (Para. 5.1) and also to Appendices 4 and 5.

TYPE 2

FORMULATIONS WHICH ARE BROADLY SIMILAR IN COMPOSITION TO EXISTING PRODUCTS ALREADY ON THE MARKET AND WHICH COULD BE CONSIDERED TO BE SUITABLE ALTERNATIVES.

These applications will require a limited application. Full clinical trials will not be required. Please refer to the Information Notes (Para.5.2). In addition, appropriate acceptability information must be provided in line with the requirements outlined in Appendix 5. Broadly similar’ refers to the ability to compare the product with other products in the same sub category.

TYPE 3

EXISTING PRODUCTS TO WHICH MINOR CHANGES (INCLUDING PRICE) ARE PROPOSED.

These applications must detail the proposed changes, providing a rationale for these changes and enclosing sample material if appropriate. Please refer to the Information Notes (Para.5.3) and Appendix 2.1 for further information.

If several Type 3 changes are requested for the same product, such that the product is significantly altered, the Applicant may be asked to submit a Type 2 application.

Changes could include
  - alterations to product formulation
    • to the fibre source or minor changes in macronutrients, vitamin, mineral, haematinic and trace element composition content to maintain compliance with UK / EC regulations.
    • to improve patient acceptability
- product name change
- changes to recommended shelf life
- instructions for reconstitution
- changes to packaging / general labelling
- changes to and/or new data sheets
- changes in cost
- changes in the manufacturing process which have an impact on the product composition and / or presentation including addition / removal of flavourings.
- changes in manufacturing location for either the product in its entirety or for any component of the product
  i. if the change(s) are within the EU then a statement confirming that the source of manufacturing has changed, advising of the new location and confirming that all existing UK / EC legislation continues to apply will be required
  ii. if the change(s) are outside the EU a statement confirming that manufacturing and quality standards continue to comply with relevant UK / EC legislation and that equivalent manufacturing accreditations and testing methodologies are in place will be required. Appropriate external certification (recognised by the UK / EC authorities) must also be submitted

**Notes:** Samples of any proposed changes to packaging, data sheet information etc must be attached to the application - please see Appendix 2.1

Type 3 Applicants must provide a sample of “actual size” labels. Electronic versions will not be acceptable. If it is not possible to submit an “actual size” label, then a sample of the product (preferably without the contents) must be provided. In this situation, i.e. when a sample is being provided, a readable label must also be submitted within the application.

Type 3 Applications will normally be submitted for Chair’s action. Applications will be processed as quickly as possible, depending on the availability of Committee members and the nature of the application.