**ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES**

**APPLICATION FORM FOR A NUTRITIONAL PRODUCT TO BE CONSIDERED BY THE ACBS**

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| **SECTION 1 – COMPANY/MANUFACTURER INFORMATION** | | |
| **1.1** | **Company Name** |  |
| **1.2** | **Company Address** |  |
| **1.3** | **Key contact** | Name: |
| Position: |
| Phone number: |
| Email: |
| Address (if different from above): |

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| **SECTION 2 – PRODUCT OVERVIEW** | | |
| **2.1** | **Current Product Name** |  |
| **2.2** | **Is the product a FSMP** | Yes  No |
| **2.3** | **If a FSMP, has it been notified to the competent authority under Regulation EU (No) 2016/128 and do you have an acknowledgement letter from DHSC?** | Yes  Please provide copy of the DHSC acknowledgement letter in Annex 1  No. Please do not submit the application. |
| **2.4** | **Is MHRA exemption required?** | Yes (provided in Annex 2)  No  Please tick to confirm that the product is not registered / nor in the process of being registered in line with the Medical Devices Directive |
| **2.5** | **Categorisation of nutritional product** |  |
| **2.6** | **Type of application** | Type 1 (please complete 2.6.1)  Type 2 (please complete 2.6.1)  Type 3 (please complete 2.6.2) |
| 2.6.1 | Has this product previously been considered/discussed by the ACBS? | Yes  No  *If ‘Yes’ – please complete 2.6.1.1 outlining the date when this product was last considered and include the ACBS Committee’s current feedback verbatim. Beneath each feedback point from the Committee state how it has been addressed, citing the relevant section of the application where amendments have been made, if applicable.* |
| **2.6.1.1 – ACBS Committee’s current feedback** | | |
| 2.6.2 | If Type 3 – provide a brief summary of the change(s) | |  |  | | --- | --- | | **Change to:** | **Brief summary of change** | | Product formulation |  | | Product name |  | | Storage |  | | Preparation or reconstitution instructions |  | | Packaging or labelling |  | | Manufacturing process |  | | Pack size |  | | Addition of new flavour |  |   Any other changes to a product are not permitted via the type 3 route. See appendix 2 of the ACBS guidance. |
| **2.7** | **ACBS Indication(s)** |  |

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| **SECTION 3 – PRODUCT INFORMATION** | | |
| **3.1** | **Product description** |  |
| **3.2** | **Appearance and form of the product**  *E.g. solid, powder, liquid, pasta, bread, biscuit* |  |
| **3.3** | **Presentation and size of individual unit**  *E.g. bottle, sachet, tin, etc. and weight/volume of unit* |  |
| **3.4** | **Presentation of secondary unit**  *(outer pack size)* |  |
| **3.5** | **Dispensing unit**  *E.g. individual, case and weight/volume of the dispensing unit* |  |
| **3.6** | **Dispensing arrangements** |  |
| **3.7** | **Flavours** |  |
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| **3.8** | **Contraindications/Precautions** |  |
| **3.9** | **Age suitability** |  |
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| **3.10** | **Storage (unopened)** |  |
| **3.11** | **Storage (opened/reconstituted) at room temperature** |  |
| **3.12** | **Storage (opened/reconstituted) in the fridge** |  |
| **3.13** | **Shelf life** |  |
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| **3.14** | **Ingredients** (please **bold** any allergens) |  |

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| **SECTION 4 – PRODUCT USE** | | | |
| **ONLY COMPLETE THE SECTION REQUIRED FOR YOUR PRODUCT** | | | |
|  | **Product presentation** | **Please indicate** |  |
| 4.1 | **Ready to consume/use - no preparation required, e.g. liquid oral nutritional supplements, tube feeds** |  | **Complete 4.1**  **Ready to consume/use products** |
| 4.2 | **Powdered product, which requires reconstitution, e.g. Powdered oral nutritional supplements, FSMP intended for infants, food and fluid thickeners** |  | **Complete 4.2**  **Powdered products requiring reconstitution** |
| 4.3 | **Specialised products in food form – ready to eat or those requiring reconstitution or cooking, e.g. low protein foods, gluten free foods, ketogenic foods** |  | **Complete 4.3**  **Specialised products in food form – ready to consume or those requiring reconstitution or cooking** |
|  | | | |
| **4.1** | **Ready to consume/use products, e.g. liquid oral nutritional supplements, tube feeds** | | |
| 4.1.1 | **Directions for use** |  | |
| 4.1.2 | **Measuring device size (if applicable)**  *e.g. measuring cup for module type ONS* |  | |
| 4.1.3 | **Route of administration**  *e.g. enteral (tube) use +/- oral etc.* |  | |
| 4.1.4 | **Recommended intake and/or use** |  | |
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| **4.2** | **Powdered products requiring reconstitution, e.g. oral nutritional supplements, FSMP intended for infants, thickeners** | | |
| 4.2.1 | **Sachet or scoop size**  *e.g. 57g sachet or 4.5g scoop* |  | |
| 4.2.2 | **Total volume of reconstituted product** |  | |
| 4.2.3 | **Number of sachets or scoops per serving/feed**  *e.g. 1 x 57g sachet = 1 serving OR please add an extra table to provide number of scoops per feed for infant formulas or feeds that have varying concentrations, or to achieve each IDDSI level for thickeners* |  | |
| 4.2.4 | **Directions for use/preparation guidelines** |  | |
| 4.2.5 | **Route of administration**  *e.g. enteral (tube) use +/- oral etc.* |  | |
| 4.2.6 | **Recommended intake and/or use** |  | |
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| **4.3** | **Specialised products in food form (ready to eat or those requiring reconstitution or cooking), e.g. low protein foods, gluten free foods, ketogenic foods.** | | |
| 4.3.1 | **Standard serving size**  *e.g. 80g pasta, 2 x 20g slices of bread* |  | |
| 4.3.2 | **Directions for use/preparation guidelines** |  | |
| 4.3.3 | **Route of administration** |  | |
| 4.3.4 | **Recommended intake and/or use** |  | |

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| **SECTION 5 – NUTRITIONAL COMPOSITION** |

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| **\*** When submitting a type 2 application, please compare the nutritional composition of your product with a product that is broadly similar in composition and intended use and is already listed in Part XV of the Drug Tariff.  **\*\*** When submitting a type 3 application with a formulation change that impacts nutritional profile, please complete both current and revised product nutritional composition to show the change in formulation | |
| **5.1** | **Nutritional profile** |
| 5.1.1 | *Complete nutritional profile information in the Section 5.1 spreadsheet. If more than one formulation forms part of this application use additional sections 5.1.1, 5.1.2, 5.1.3 etc.*  A copy of the nutritional profile spreadsheet has been provided in Annex 3  No change in nutritional profile |

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| **5.2** | **Protein hydrolysis** | |
| 5.2.1 | **Do you need to provide information about any protein hydrolysis?** | Yes (complete sections 5.2.2-5.2.6)  No |
| **Protein a** |  |  |
| 5.2.2(a) | Whole protein source |  |
| 5.2.3(a) | Degree of hydrolysis, i.e. chain lengths |  |
| 5.2.4(a) | Source of enzymes used for hydrolysis |  |
| 5.2.5(a) | Proportion as free amino acids |  |
| 5.2.6(a) | Is there is any trace of enzyme or whole proteinremaining in the product? |  |
| **Protein b** |  | |
| 5.2.2(b) | Whole protein source |  |
| 5.2.3(b) | Degree of hydrolysis, i.e. chain lengths |  |
| 5.2.4(b) | Source of enzymes used for hydrolysis |  |
| 5.2.5(b) | Proportion as free amino acids |  |
| 5.2.6(b) | Is there is any trace of enzyme or whole proteinremaining in the product? |  |
| **5.3** | **Carbohydrate hydrolysis** | |
| 5.3.1 | **Do you need to provide information about any carbohydrate hydrolysis?** | Yes (complete sections 5.3.2-5.3.6)  No |
| **CHO a** |  |  |
| 5.3.2(a) | Carbohydrate source |  |
| 5.3.3(a) | Source of enzymes used for hydrolysis |  |
| 5.3.4(a) | Is there is any trace of enzyme remaining in the product? |  |
| **CHO b** |  | |
| 5.3.2(b) | Carbohydrate source |  |
| 5.3.3(b) | Source of enzymes used for hydrolysis |  |
| 5.3.4(b) | Is there is any trace of enzyme remaining in the product? |  |
| **5.4** | **Nutritionally complete volume** | |
| 5.4.1 | **Is this product nutritionally complete?** | Yes (complete sections 5.4.2-5.4.3)  No |
| 5.4.2 | **Nutritionally complete volume for:** |  |
|  | 1-3 year old child |  |
|  | 4-6 year old child |  |
|  | 7-10 year old child |  |
|  | 19-49 year old adult |  |
| 5.4.3 | A copy of the completed nutritionally complete comparison spreadsheet has been provided in Annex 4. | |

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| **SECTION 6 – PRODUCT DOCUMENTATION** | |
| **Product data sheet** **for healthcare professionals** | |
| 6.1 | A copy of the data sheet has been provided in Annex 5. |
| **Manufacturing process and quality control mechanisms** | |
| 6.2 | A copy of current and appropriate external certification which is recognised by the UK / EC has been provided in Annex 6. |
| **Labelling and packaging** | |
| 6.3 | A copy of the labels for all unit sizes for products have been provided in Annex 7, including labelling for secondary / cluster packaging.  (Type 3 applications only) In addition, a copy of the current labels for all unit sizes for products have been provided in Annex 7 including labelling for secondary / cluster packaging, and are clearly identified as such. |
| 6.3.1 | (Type 3 applications only)Provide a brief summary of the change(s) to the labels: |

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| **SECTION 7 – SUPPORTING CLINICAL EVIDENCE to be included in Annex 8** | | |
| **7.1** | **Type 1 applications only** | A detailed report of the completed clinical trial of the product, including information on acceptability, which demonstrates its therapeutic usefulness in the management of disease in the community for the indications sought.  An abstract of the completed clinical trial, which must include full references to directly relevant papers from peer reviewed journals. |
| **7.2** | **Type 2 applications only** | A detailed report of the completed study which demonstrates the product’s acceptability.  An abstract describing published clinical trials of any similar products (which could be considered to be suitable alternatives) including directly relevant references from peer reviewed journals that demonstrate their therapeutic usefulness in the management of disease in the community for the indications sought. |
| **7.3** | **Type 1 and 2 applications** | full copies of two relevant papers from the peer reviewed journals as cited within the abstracts described above. |
| **7.4** | **Type 3 only if required** | A report where required by, and in accordance with, the guidance. |

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| **SECTION 8 – PRICE** | | | |
| **8.1** | **Price** (inclusive of all distribution costs) | |  |
| **8.2.1** | (Type 2 applications only)  **Comparator product name** | |  |
| **8.2.2** | (Type 2 applications only)  **Comparator product price** | |  |
| **8.3** | **Price rationale** | |  |
| **SECTION 9 – DECLARATIONS** | | | |
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|  | | The statements below must be signed and dated by an appropriately competent and authorised individual describing their status and accepting legal responsibility for the validity of the evidence provided on behalf of the Applicant.  I declare that the information given in this application and accompanying papers is correct and complete and that it conforms with the accompanying guidance (to the best of my knowledge). On behalf of the applicant, I accept legal responsibility for the accuracy of all the information provided and confirm that the application conforms to all legal requirements.  I undertake to notify / apply to the ACBS of / for approval of any changes in the product or its price, presentation, packaging or marketing.  I understand that, should the ACBS recommend that this product should not be available for prescription at NHS expense, the Department of Health will be notified and the product may be added to Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs) Regulations 2004.  I understand that the information I have provided on this application form will be kept on a password-protected database, accessible by Committee members, select DHSC staff and MHRA staff that are part of the Borderline Team. I understand I can request more information on the processing of data by emailing the Committee’s Secretariat. I agree to the information in this application form being stored and accessed in this way.  If the product is approved, I undertake that it will only be promoted to prescribers at NHS expense for those conditions recommended by the ACBS and understand the ACBS may review the product at any time and may request a re-application.   * On behalf of the applicant, I accept legal responsibility for the accuracy of all the information provided regarding the manufacturing process and quality control mechanisms and confirm that the manufacturing and quality control mechanisms conform to all legal requirements. If there is a change to the location in which the product, or any component of the product, is manufactured, I confirm that this will continue to comply with the relevant UK legislation. * On behalf of the applicant, I confirm that all ingredients comply with the relevant UK legislation and accept responsibility for the accuracy of the information. * On behalf of the applicant, I confirm that all the labelling complies with the UK regulations and accept legal responsibility for the accuracy of the labelling information. * On behalf of the applicant, I accept legal responsibility for the accuracy of the clinical evidence provided to support this application, and confirm that the application conforms to all legal requirements   For Type 3 applications for products for Inherited Metabolic Disorders ONLY:   * On behalf of the applicant, I confirm that when a new flavour of a product or an amended formulation that impacts flavour is submitted as a Type 3 application for a product intended for the management of an inherited metabolic disorder and already listed in Part XV of the Drug Tariff the following has been undertaken: * Consulted both adult and paediatric IMD dietitians (when applicable) and patients from relevant age groups (adult/paediatric) about the current flavour range and any future flavours that are developed. Evidence of such consultations will be made available for the ACBS committee to review on request. * Ensure that patients have had the opportunity to taste the range of flavours and have agreed their palatability. Evidence of taste testing will be made available for the ACBS committee to review on request. | |
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|  | | **Signed on behalf of the company:**  **Name: Status:**  **Signature: Date:** | |

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| **SECTION 10 – ATTACHMENTS TO APPLICATION FORM** | | | |
| **Annex** | **Corresponding Section** | | **Included within this application (Y/NA)** |
| 1 | 2.3 | Acknowledgement letter from DHSC |  |
| 2 | 2.4 | MHRA exemption if required |  |
| 3 | 5.1 | Nutritional profile table |  |
| 4 | 5.4.3 | Nutritionally complete table |  |
| 5 | 6.1 | Product data sheet for healthcare professionals |  |
| 6 | 6.2 | Manufacturing certification |  |
| 7 | 6.3 | Product labels |  |
| 8 | 7.1-7.4 | Supporting clinical evidence |  |