

ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

APPENDIX 2.1

EVIDENCE REQUIRED FOR TYPE 3 NUTRITIONAL APPLICATIONS

- **Each application must include an Application Summary Form.**
- **Applicants need only supply copies of the evidence relating to the relevant original paragraphs of the Information Notes as indicated below.**
- **Samples of “actual size” labels MUST be provided. An electronic version will not be acceptable.**

Nature of change	Evidence required	Paragraphs to be attached from the Information Notes / Other reference
Product formulation	<p>Proposed changes and the reasons for these together with supporting clinical evidence</p> <p>A statement confirming that all other elements of the nutritional composition remain unchanged will be required</p> <p>Both the old and the new formulations must be attached with the changes highlighted</p> <p>A sample of both the old and any new “actual size” labels (non-electronic) / data sheets must be provided</p>	<p align="center">4.1.1, 4.1.2, 4.1.3, 4.1.4 (<u>all</u> information will be needed unless the ingredient listing is unchanged in which case 4.1.1 need not be completed)</p> <p align="center">4.2 Information relevant to proposed change only</p>

Nature of change	Evidence required	Paragraphs to be attached from Information Notes / Other reference
New flavours of an approved product	<p>Details of proposed additional flavour with supporting clinical evidence</p> <p>A sample of the new “actual size” label (non-electronic) and data sheet must be provided</p>	<p>4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2</p>
Product name change	<p>Proposed name and reason for the change</p> <p>Note: If the formulation is also changed, both the old and the new formulations must be attached with the changes highlighted</p> <p>A sample of any new “actual size” label / data sheet (non-electronic) must be provided</p>	<p>Summary sheet</p> <p>4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2 Information relevant to the proposed change only</p>

<p>Instructions for reconstitution</p>	<p>The new instructions and the reason for the change</p> <p>A sample of any new “actual size” labels (non-electronic) must be provided if appropriate</p>	<p>4.4.1</p>
<p>Packaging and general labelling</p>	<p>Details of any proposed changes including pack size</p> <p>A statement will also be needed to confirm that any changes comply with extant UK / EC legislation</p> <p>A sample of any new “actual size” labels (non-electronic) must be provided</p>	<p>9.1, 9.2</p>
<p>Data Sheets</p>	<p>Copies of any proposed changes / new data sheets together with a formal and signed statement confirming that any new literature will be used appropriately and that it complies with current relevant legislation</p> <p>A sample of any new “actual size” label / data sheet must be provided if appropriate</p>	<p>4.1.2, 4.1.4</p>

Changes in the manufacturing process	Appropriate information about any changes in the manufacturing process must be provided together with a formal, signed statement	4.3, 5.3.4
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