

ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

APPENDIX 2.1

EVIDENCE REQUIRED FOR TYPE 3 DERMATOLOGICAL APPLICATIONS

- Applicants need only supply copies of the evidence relating to the relevant original paragraphs of the Information Notes as indicated below
- ALL changes must include a statement of the total cost to the NHS as detailed in the Information Notes (Para 13)
- Samples of “actual size” labels MUST be provided. An electronic version will not be acceptable

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

<p>Product name change</p>	<p>Proposed name and the 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 attached</p>	<p>Summary sheet</p> <p>4.1.1, 4.1.2, 4.1.3, 4.2 Information relevant to the proposed change only</p>
<p>Product shelf life</p>	<p>Revised shelf life statement and the rationale for this</p> <p>A sample of any new “actual size” label / data sheet (non-electronic) must be attached</p>	<p>4.5</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>10, 11</p>
<p>Changes in the manufacturing process and / or changes in the location of manufacture</p>	<p>Appropriate information about any changes in either the manufacturing process or the manufacturing location(s) must be provided together with a formal, signed statement</p>	<p>4.3, 5.3.4</p>