ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

APPENDIX 2

TYPE OF APPLICATION

TYPE 1

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

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.

Note: 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 ARE PROPOSED.

Note: These applications must detail the cost of the product and the proposed changes, providing a rationale for these changes and enclosing sample material if appropriate. Please refer to Appendix 2.1 for further information.

Changes could include:

- alterations to product formulation
- product name change
- changes to recommended shelf life
- changes to packaging / general labelling
- changes to or new data sheets
- changes in cost
- changes in the manufacturing process which have an impact on the product composition and / or presentation

- 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” label. 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.

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