ADVISORY COMMITTEE ON BORDERLINE SUSTANCES

APPENDIX 4

CLINICAL TRIAL INFORMATION TO BE PROVIDED FOR TYPE 1 (NEW PRODUCTS) APPLICATIONS

Notes: **Clinical trial data will only be required by the ACBS if there is a well-characterised use for a product which is not available from a medicinal product (with a product licence) or from BP preparations.**

These studies must conform with the principles of good clinical practice (Ref: EC Directive 2001 / 20 / EC)

Applicants are advised that further information may be sought if a company wishes to clarify particular points contained in this Appendix. No face to face meetings / telephone conversations will be held with Applicants. Correspondence must be conducted via e-mail, through the Secretariat. This is to ensure transparency and a clear audit trail.

1. Evidence for the efficacy of a dermatological product should be based on human and not animal studies, and *must* clearly demonstrate the clinical efficacy and safety of the product in question. Ideally such trials should be carried out in the community. However, in many cases this may be neither practicable nor possible. In these situations trials may be carried out within the hospital setting but the results of these should be translatable into the community.

2. Details of the trial protocol should be attached to the eventual submission for the Committee's consideration. The submission should state both the intention of the trial and its actual outcome. Outcome variables within the trial should be relevant to the product and its indications. Whenever possible, the trial product should be compared with a standard formulation.

Data should be presented in the form of a paper including an abstract as would be submitted for peer reviewed publication in the journal of a learned society. Appropriate references must be given and raw data generated by the trial should be appended as necessary to support the paper.

Clinical trials must have ethical approval from a committee composed in accordance with Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants (4th edition, Royal College of Physicians, 2007).

3. A detailed trial which lasts for at least four weeks will be expected. Primary and secondary endpoints should be outlined a*nd* the trial should include relevant observations. The trial should meet normal statistical requirements to demonstrate the efficacy and safety of the new product.

Greater evidence of dermatological specificity will be required for a product specifically intended for infants and young children.

4. Carefully planned and controlled trials should meet normal statistical requirements to demonstrate the clinical value of the product in question. The trial reports should give, *as a minimum*:

(a) The sex, age and, usually, ethnic origin of each patient

(b) The number of days during the trial on which each patient received the product and the control product

(c) Whether there were any adverse reactions and what these constituted.

5. The views of the patients as well as those of professionals about the value of and suggested indications for the use of the product should only be given when absolutely relevant, specific and appropriate.

6. The submission to the Committee should demonstrate either the particular advantages of the product in question or state that it is a suitable alternative to other products which certain patients or patient groups may be unable to tolerate.