



Bijlage D METC - SOP

LETTER OF APPROVAL

APPENDIX *

On * the Independent Ethics Committee (Medisch Ethische ToetsingsCommissie) of the Foundation 'Evaluation of Ethics in Biomedical Research' (Stichting BEBO), Assen, The Netherlands, approved the dossier with * code * (see Appendix I), and protocol entitled:

' study title'*

From the information provided by the investigator on ** it became apparent that the following documents have been made to above-mentioned Protocol after the original date of approval:

- A1 Cover letter to the IEC, dated **
- B1 ABR Form version **, for CCMO-dossier NL**, dated **
- B3 EudraCT Application Form, dossier **, dated **
- B5 Substantial Amendment Notification Form, dated **

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The Committee feels that this Amendment does not affect the safety of the participants, nor does it affect the adequacy of the Protocol.

Therefore, the Committee does not see any reason to reconsider its previous approval.

This appendix is an integral part of the original Letter of Approval and the same conditions and timelines apply for filing a notice of objection.

Assen, *

J.R.J.B. Brouwers, Ph.D., Pharm.D. or
B. Wilffert, Ph.D., Pharm.D.
(chairman)