SUBMISSION OF COMMENTS ON DRAFT COMMISSION PAEDIATRICS GUIDELINE
COMMENTS FROM PIERRE FABRE MEDICAMENT / Emmanuelle STOECKEL-BELLEMIN
GENERAL COMMENTS
The Annex to this draft guideline (i.e. the application form) to be filled in was not included.

SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION TITLE		
Section. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
Section 1, § 1.1	It is understood that when an applicant intends to develop several indications simultaneously, only one comprehensive PIP should be included in the application, and that rewards for the applicant will be granted when all the agreed requirements are fully met. The question remains for extension to existing marketing authorisations (i.e. new formulation, new indication) : should the PIP cover all already approved indications and formulations, i.e. should the paediatric development cover all approved indications and formulations for obtaining 6-month extension protection ?	

Please feel free to add more rows if needed.

Date of transmission:

Submit all comments to: by email to peter.arlett@ec.europa.eu in word forma please.
Deadline for comments: <30 March 2007>
These comments and the identity of the sender may be published on the European Commission website unless a specific justified objection is received by the European Commission.