European Medicines Agency

SUBMISSION OF COMMENTS ON "Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial" Draft Revision 3, […] 2009

ENTR/F/2/SF D(2009)

COMMENTS FROM LFB BIOTECHNOLOGIES, Françoise ROSSI Regulatory Strategy Director
GENERAL COMMENTS

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE		
Line no[1]. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
Section 1.1 legal basis …… [Member states and persons requesting authorisation of a clinical trial, substantially amending a protocol of a clinical trial, and declaring the end of a clinical trials shall consider this guidance when applying Directive 2001/20/EC and its implementing acts guidance]	Be aware that a substantial amendment could modify another document, not only the protocol: the IMPD for example. This is not clear in this section. The explanation is only given page 22 of this document : Section 3.2 the notion of "amendment": *Article 10(a) of directive 2001/20/EC refers only to "amendments to the protocol". This is to be understood as encompassing all documentation submitted in the context of the submitted protocol.* Please position this paragraph at the beginning of the section 1.1	

[1] Where available

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Section 2.2 "In addition, the applicant should draw attention to any scientific advice related to the trial or IMP given by the European Medicines Agency (“EMEA”) or the national competent authority of the Member State concerned or any other country and indicate where the copy of the advice is contained in the application".	We understand the need to be aware of scientific advice related to the trial or IMP given by European Authorities, but not given by any other country. It may be confusing because the requirements may be different according to the region.	"In addition, the applicant should draw attention to any scientific advice related to the trial or IMP given by the European Medicines Agency (“EMEA”) or the national competent authority of the Member State concerned ~~or any other country~~ and indicate where the copy of the advice contained in the application".
Section 2.10 Other documents to be submitted "If applicable and available, the Paediatric Investigation Plan (“PIP”) summary report, the opinion of the Paediatric Committee and the decision of the EMEA."	To clarify what is required: Scientific Documentation (Section B to F, without the appendices) including the EMEA/Rapporteur/Peer-reviewer and PDCO comments?	"If applicable and available, the approved Paediatric Investigation Plan (“PIP”) ~~summary report~~, the opinion of the Paediatric Committee and the decision of the EMEA."

Please feel free to add more rows if needed.