

## ROSSIGNOL Nicolas (ENTR)

---

**From:** GIRARDET Sylvie [girardets@lfb.fr]  
**Sent:** mardi 10 juin 2008 14:31  
**To:** ROSSIGNOL Nicolas (ENTR)  
**Cc:** ROSSI Françoise; MARBOEUF Florence; RENOUF Sébastien  
**Subject:** IMPLEMENTATION OF THE 'ADVANCED THERAPIES' REGULATION\_Comment from LFB  
**Importance:** High  
**Attachments:** Advanced therapies-Consultation-paper-nr\_2008-04-08.pdf

[On behalf of Françoise Rossi - Regulatory Strategy and Developpement Director](#)

Dear Mr Rossignol,

I am pleased to provide you with LFB's comment on **PROPOSALS TO AMEND ANNEX I TO DIRECTIVE 2001/83/EC AS REGARDS ADVANCED THERAPY MEDICINAL PRODUCTS.**

*Page 5:*

### *2.2. Definitions*

#### *2.2.1. Gene therapy medicinal product*

*means a medicinal product:*

*- that contains or consists of a nucleic acid sequence used in or administered to human beings, in vivo or ex vivo, with a view to regulating, repairing or replacing a targeted genetic sequence; and*

*- whose therapeutic, prophylactic or diagnostic effect relates directly to the nucleic acid sequence it contains, or to the product of genetic expression of ~~this sequence~~ the contained sequence.*

We remain at your disposal for any clarification you may require.

Best regards,

Françoise Rossi  
[rossi@lfb.fr](mailto:rossi@lfb.fr)  
LFB Biotechnologies  
3, avenue des Tropiques  
BP 305 - Les Ulis  
91958 Courtaboeuf Cedex  
France  
Phone: + 33 (0)1 69 82 7057

---

Ce message et toutes les pieces jointes (ci-apres "le message") sont confidentiels et sont adresses a l'attention exclusive de ses destinataires. Toute divulgation, utilisation, diffusion ou reproduction (totale ou partielle) du message, ou des informations qu'il contient, doit etre prealablement autorisee par l'expediteur. Tout message electronique est susceptible d'alteration et son integrite ne peut etre assuree. Le Laboratoire francais du Fractionnement des Biotechnologies (LFB) decline toute responsabilite au titre de ce message s'il a ete modifie ou falsifie. Si vous n'etes pas destinataire de ce message, merci de le detruire immediatement et d'avertir l'expediteur de l'erreur de distribution et de la destruction du message.

8/07/2008

This e-mail and all the enclosures (hereafter "the message") are confidential and are addressed to the exclusive attention of its recipients. Any disclosure, use, diffusion or reproduction (either whole or partial) of the message, or information which it contains, must be authorized beforehand by the sender. E-mails are susceptible to alteration and their integrity cannot be guaranteed. The Laboratoire français du Fractionnement et des Biotechnologies (LFB) declines any responsibility under this message if it were modified or falsified. If you are not the intended recipient of this message, please delete it immediately from your system and notify the sender of the wrong delivery and the mail deletion.