

ROSSIGNOL Nicolas (ENTR)

From: Niamh Brosnan [nbrosnan@archemix.com]
Sent: lundi 9 juin 2008 22:34
To: ROSSIGNOL Nicolas (ENTR)
Cc: Niamh Brosnan
Subject: Archemix Response to Regulation (EC) No 1394/2007 Implementation of the 'Advanced Therapies' Regulation

Dear Mr. Rossignol,

Archemix has reviewed the public consultation paper entitled, "Proposals to Amend Annex I to Directive 2001/83/EC as Regards Advanced Therapy Medicinal Products," dated 8 April 2008. We note that aptamers (oligonucleotides selected for their ability to bind to specific non-nucleic acid targets) are not and should not be included in the definition of gene therapy medicinal products.

Therefore aptamers do not fall under the scope of the proposed regulation. We urge the Commission, however, to more clearly define gene therapy medicinal products based on their functionality and not their composition so as to avoid the inadvertent inclusion of oligonucleotide therapies such as aptamers.

Please don't hesitate to contact me if you have any questions.

Best regards,

Niamh Brosnan

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