

ROSSIGNOL Nicolas (ENTR)

From: Thomas Schulze [t.schulze@avontec.com]
Sent: mardi 3 juin 2008 9:24
To: ROSSIGNOL Nicolas (ENTR)
Cc: 'Gerhard Breipohl'; 'Christine Mehrl-Guerke'
Subject: Avontec decoy ODNs/ gene therapy medicinal products

Dear Nicolas Rossignol,

Avontec GmbH is a Biopharmaceutical Company based in Martinsried, Germany, which develops fully synthetic short double-stranded DNA oligonucleotide decoys which attenuate the activity of transcription factors proteins.

The drug substances in development are fully synthetic DNA oligonucleotides which are chemically synthesized using well established and controlled chemical processes. The synthesis uses well controlled starting materials from a well controlled supply chain.

The quality of the drug substances and drug products is controlled by applying state-of-the-art analytical methods.

The drug substances and drug products have proven to be safe in numerous toxicological studies and also a number of clinical trials.

Avontec therefore respectfully requests that oligonucleotides manufactured by chemical synthesis should explicitly be excluded from the scope of gene therapy medicinal products as defined in "Proposals To Amend Annex I To Directive 2001/83/EC As Regards Advanced Therapy Medicinal Products" Version: 8 April 2008 (Regulation (EC) No 1394/2007).

If further questions arise concerning our comment please feel free to contact us.

Best regards,

Thomas

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Chief Executive Officer

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