

**FOI 23/326 - Fluenz Tetra nasal spray suspension Influenza vaccine (live attenuated, nasal) made by AstraZeneca**

Dear

Thank you for your email of 1st May where you have asked "*please provide the following information for the Fluenz Tetra nasal spray suspension Influenza vaccine (live attenuated, nasal) made by AstraZeneca UK LTD.*

- 1. The testing protocol for this influenza vaccination prior to its use on children?*
- 2. The efficacy of this influenza vaccination in preventing serious illness?*
- 3. The side effects experienced during the testing protocol and use of this influenza vaccination?*
- and 4. What exactly are the genetically modified organisms (GMO) contained within this influenza vaccination?"*

The marketing authorisation for Fluenz Tetra was authorised by the European Medicines Agency (EMA) through a centralised procedure (EMEA/H/C/002617). Further information on Fluenz Tetra is available through the EMA via the following link (including the EMA's Public Assessment Reports of the data received):

<https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fmedicines%2Fhuman%2FEPAR%2Ffluenz-tetra&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cc3fa773d305d4ecae04c08db62bd16e9%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638212336492446517%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IjEhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=61Vs706FIJaUcotekq8bwMjPTQrGusO%2FnTG88dm52ow%3D&reserved=0>

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office

Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre  
Communications and engagement team  
Medicines and Healthcare products Regulatory Agency  
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