From: SANTE PHARMACEUTICALS B5
Sent: mercredi 28 octobre 2020 09:50

To:

Subject: Holding reply - RE: Conditional marketing authorization process of the orphan

medicine "Zynteglo"

Dear

We refer to your e-mail dated 15/10/2020 in which you make a request for revocation, suspension or review of the conditional marketing authorisation of "Zynteglo".

We would like to inform you that we are currently analysing your submission. Unfortunately, we will not be in a position to provide you with a reply within the time limit of 15 working days as foreseen in accordance with better administrative practices. We will however revert to you in due course.

We apologise for this delay and for any inconvenience this may cause.

Kind regards,

Unit "Medicines: policy, authorisation and monitoring"



**European Commission**DG Health and Food Safety

This message represents solely the views of its author and can not be regarded as the official position of the Commission. It is intended solely for the person to whom it is addressed and may contain confidential information. If you have received this message in error, please notify me as soon as possible.

From:

Sent: Thursday, October 15, 2020 10:26 PM

To: GALLINA Sandra (SANTE) < @ec.europa.eu>; SANTE DG <SANTE-DG@ec.europa.eu>

Cc:

Subject: I: Conditional marketing authorization process of the orphan medicine "Zynteglo"

Dear Ms Gallina,

We have just been informed that retired from the European Commission and requested to contact you as Acting General Director.

Therefore, in the name and on behalf of Errant Gene Therapeutics, LLC, we wish to bring also to your attention, as Acting General Director, the attached application in relation to the pending conditional marketing authorization of the orphan medicine "Zynteglo" manufactured by the company Bluebird Bio B.V. (Netherlands) and its future renewal process.

Yours faithfully,

Das

Inviato: giovedì 15 ottobre 2020 19:43

Δ.

Oggetto: Automatic reply: Conditional marketing authorization process of the orphan medicine "Zynteglo"

Dear,

I have now retired from the European Commission.

For any work related matters please contact the Acting Director General,

@ec.europa.eu, cc sante-dg@ec.europa.eu

For private and personal matters, please contact me via

or

Thank you.

Best regards.

Le informazioni contenute nella comunicazione che precede sono riservate e destinate esclusivamente alla persona o all'ente sopraindicati. La diffusione, distribuzione e/o copiatura del presente email o di qualsiasi documento allegato da parte di qualsiasi soggetto diverso dal destinatario e' proibita. La sicurezza e la correttezza dei messaggi di posta elettronica non possono essere garantite. Se avete ricevuto questo messaggio per errore, Vi preghiamo di contattarci immediatamente. Grazie.

The content of this email is confidential and it is intended for the sole use of the addressees. The transmission, distribution and/or copy of this email or any document attached hereto by any person other than the addresses is prohibited. The transmission of this email cannot be guaranteed to be secure or error-free. If you have received this communication unintentionally, please inform us immediately. Thank you.