

PHONE LOG
OFFICE OF THE GENERAL COUNSEL

DATE OF MEETING: March 4, 2024

LOG ENTRY SOURCE: Austin Schlick (Executive Director)

COMMISSION ATTENDEES: Austin Schlick

NON-COMMISSION ATTENDEES: Sarah Wilson – Covington & Burling LLP

SUMMARY OF CONVERSATION:

Ms. Wilson called on behalf of Genentech, in connection with Genentech's Petition to Exempt Baloxavir Marboxil (XOFLUZA™) in 40 mg and 80 mg Tablet Doses from Special Packaging Requirements of the Poison Prevention Packaging Act. The conversation was consistent with the following email message:

From: Wilson, Sarah

To: Schlick, Austin

Subject: Call re. XOFLUZA Petition

Date: Tuesday, March 12, 2024 6:26:08 PM

Austin,

>

> Thank you very much for your time last week to discuss the status of the rulemaking to implement the exemption of XOFLUZA from child-resistant packaging requirements. As I noted on the call, Genentech plans to continue packaging XOFLUZA for the U.S. market in the Pennsylvania facility. The company has discussed its plans to continue U.S. production and packaging of XOFLUZA in conversations with the Administration for Strategic Preparedness and Response regarding the Strategic National Stockpile. Genentech intends to add a back-up packaging site in Kaiseraugst, Switzerland, for the U.S. market. This facility would be used as a back-up facility, for example, in the event that there is a spike in demand for XOFLUZA over a short period of time.

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> Please let me know if you have any additional questions.

>

> Best regards,

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> Sarah

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> Sarah Wilson

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> [https://urldefense.us/v3/_http://www.cov.com_!!K4v5ATkRwarYYQ!3MaXkzsZALquZ5iHce1kszuS5J1tKNyBoSWDm86RTq_JC-](https://urldefense.us/v3/_http://www.cov.com_!!K4v5ATkRwarYYQ!3MaXkzsZALquZ5iHce1kszuS5J1tKNyBoSWDm86RTq_JC-2MmT_pj8iH-Y_7apP9aorLVVv05dkwjs$)

> [2MmT_pj8iH-Y_7apP9aorLVVv05dkwjs\\$](https://urldefense.us/v3/_http://www.cov.com_!!K4v5ATkRwarYYQ!3MaXkzsZALquZ5iHce1kszuS5J1tKNyBoSWDm86RTq_JC-2MmT_pj8iH-Y_7apP9aorLVVv05dkwjs$)

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