

From: [Janice Castillo](#)  
To: [Gildner, Jean](#)  
Cc: [Giordano, Erica](#)  
Subject: Re: BLA 125586 Carton and labeling comments  
Date: Thursday, April 26, 2018 12:07:44 PM  
Attachments: [image001.png](#)

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Receipt acknowledged.  
Thank you.  
Janice

Sent from my iPhone

On Apr 26, 2018, at 8:23 AM, Gildner, Jean <[Jean.Gildner@fda.hhs.gov](mailto:Jean.Gildner@fda.hhs.gov)> wrote:

Dear Janice,

Please see the following comments:

- <!--[if !supportLists]-->1. <!--[endif]-->Your proper name includes the suffix -zhzo.  
Revise your proper name on both the carton and container labels to:  
coagulation factor Xa (recombinant), inactivated-zhzo
- <!--[if !supportLists]-->2. <!--[endif]-->For the carton label, add the lot number  
and expiration date information. Also, revise the phrase "preservative free" to  
the regulatory statement "contains no preservative"

Please acknowledge receipt of this email.

Sincerely, Jean

*Jean F. Gildner* MSHS, MT (ASCP)

**Regulatory Project Manager**  
**Center for Biologics Evaluation and Research**  
**Office of Tissues and Advanced Therapies**  
**U.S. Food and Drug Administration**  
Tel: 240-402-8296  
[jean.gildner@fda.hhs.gov](mailto:jean.gildner@fda.hhs.gov)

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#) [<image005.jpg>](#)  
[<image006.jpg>](#)

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