

APPROVED

By Jean Gildner at 12:52 pm, Nov 02, 2017

From: [Gildner, Jean](#)
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)
Subject: BLA 125586 Portola Information Request
Date: Thursday, November 02, 2017 12:48:12 PM
Attachments: [image001.png](#)

Dear Janice,

Please see the following information request. Please respond as soon as possible. If you have any questions please feel free to contact me. Please acknowledge receipt of this email.

The accelerated approval regulation (21 CFR 601.45) requires that Portola submit to FDA, during the preapproval review period, all advertising and promotional labeling intended for distribution in the first 120 days following approval. In addition, after approval, promotional items intended for dissemination after the first 120 days following approval must be submitted 30 days prior to the anticipated distribution date.

You submitted preapproval draft promotional materials during your first review cycle, please indicate whether you intend to submit new promotional materials in place of the earlier materials. Please provide a timeline for submitting the preapproval draft submissions.

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



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.