

From: Krissy.Carrington@sanofi.com [mailto:Krissy.Carrington@sanofi.com]
Sent: Friday, July 27, 2018 3:01 PM
To: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Cc: Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>
Subject: RE: STN #125563 -Request for proposed suffixes

Dear Kelsy,

Thank you for the email. I acknowledge receipt and will assure a response is returned to you by 06 Aug 2018. Kind regards,

Krissy

From: Hoffman, Kelsy [mailto:Kelsy.Hoffman@fda.hhs.gov]
Sent: Friday, July 27, 2018 2:05 PM
To: Carrington, Krissy /CA
Cc: Ramachandran, Girish
Subject: [EXTERNAL] STN #125563 -Request for proposed suffixes

Dear Ms. Carrington:

Your application falls within the scope of the Guidance to Industry entitled [Nonproprietary Naming of Biological Products](#). This Guidance describes FDA's current thinking on the need for biological products licensed under the Public Health Service Act (PHS Act) to bear a nonproprietary name that includes an FDA-designated suffix.

An applicant may submit up to 10 proposed suffixes in the order of your preference as described on the guidance. The final determination on the acceptability of a proposed suffix is based on FDA's review of the information you submit.

Intimately should you choose not to submit a suffix(es) for FDA review, FDA will assign a suffix for inclusion in the proper name designated in the license at the time FDA approves the application.

Please submit your proposed suffixes as an amendment to your BLA STN 125563/0 within 10 days of this request or let us know immediately should you prefer the FDA assigns a suffix.

Thank you,
Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
Kelsy.Hoffman@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 immediately by e-mail or phone.