

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Portola FDA Comments Re: Suffix
Date: Wednesday, April 04, 2018 8:35:49 PM
Attachments: [image007.png](#)

Jean,

Portola proposes an alternative list of suffixes below. However, should time constraints not allow for evaluation of these suffixes, we would chose [ZHZO](#) from the FDA list.

ZXPA

PAXI

APXI

INHX

APXZ

Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Wednesday, April 04, 2018 12:05 PM
To: Janice Castillo
Subject: BLA 125586 Portola FDA Comments Re: Suffix

Dear Janice,

Please see the following comments in regards to the list of suffixes you submitted to the FDA:

*FDA has determined that each of your proposed proper name suffixes are not devoid of meaning because each suffix either connotes the proprietary name, ANDEXXA, for this product (e.g., andx, anex, **anxx, anxx, anxa, axxn, adxx**), connotes the product's drug substance, factor Xa, (e.g., andx, anex, annx, anxx, anxa, axxn, adxx), or directly references Portola and your product (e.g., pxxa). Thus, these proposed suffixes are each inconsistent with the principles described in our final guidance and unacceptable for inclusion in the proper name of this proposed product.*

*Because the proposed suffixes were found unacceptable, and given the time constraints, we **recommend that you use one of FDA's** randomly-generated, pre-screened suffixes for inclusion in the proper name of your product.*

Please choose one of the following FDA-generated suffixes: zhzo, sjbg, knkq

Please notify me of receipt of this email and suffix you wish to select. If you have any questions please feel free to contact me.

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



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