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*APPLICATION NUMBER:*

**208264Orig1s000**

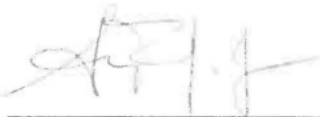
**ENVIRONMENTAL ASSESSMENT**

Date: February 4, 2015

**NDA 208264 (TEPADINA®)**  
**ENVIRONMENTAL ASSESSMENT EXCLUSION**

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ADIENNE SA claims a categorical exclusion from the requirement for preparing an environmental assessment. This is based on 21 CFR 25.31(b), which allows a categorical exclusion for an action on an NDA, since it was determined that the product is under the acceptable limit: specification - the estimated concentration of the substance at the point of entry into the aquatic environment is below 1 part per billion (ppb).



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**Dr. Antonio Francesco Di Naro**  
**President**  
**ADIENNE SA**

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/s/  
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03/08/2017