

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

21

**ENVIRONMENTAL ASSESSMENT**

**Module 1.3.7 Environmental Impact**  
[21CFR314.50(d)(1)(iii)]

**Claim for Categorical Exclusion of Environmental Assessment**

According to 21 CFR §25.15 (a) and §25.15 (d)

Pfizer Inc claims categorical exclusion from Environmental Assessment, according to 21 CFR §25.31(b), for EXUBERA® (insulin [rDNA origin] powder for oral inhalation), as the action on NDA 21-868 will increase the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

Furthermore, Pfizer Inc is unaware of any extraordinary circumstances for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment or that would adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.

The undersigned certifies that the information presented is true, accurate, and complete to the best knowledge of Pfizer Inc:



Richard T. Williams, Ph.D.  
Senior Research Fellow  
Pfizer Global Research and Development

19-NOV-2004

Date

Charles Sant Maria  
on behalf of Richard T. Williams

19-NOV-2004