

**ENVIRONMENTAL ASSESSMENT**

**BLA # 125742**

**BNT162b2**

0.45 mL Suspension for Injection, Multi-Dose Vial

Pfizer-BioNTech's BNT162b2 is a novel vaccine for the prevention of COVID-19 disease caused by the SARS-CoV-2 virus. BNT162b2 consists of highly purified single-stranded messenger RNAs encapsulated into lipid nanoparticles.

**Claim for Categorical Exclusion According to 21 CFR Part 25.15 (a), (d)**

Pfizer-BioNTech claim a categorical exclusion to the environmental assessment requirements in compliance with categorical exclusion criteria 21 CFR Part 25.31 (c); action on an application for marketing approval of a biological product, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites or degradation products in the environment. The active ingredient of the proposed product, BNT162b2, is recognized as a naturally occurring substance. Pfizer-BioNTech claims that, to the best of our knowledge, no extraordinary circumstances exist.

Preparer:

(b) (6) Principal Scientist, Environmental Sciences, Pharmacokinetics, Dynamics and Metabolism, Pfizer Worldwide R&D. M.Sc. in Toxicology; Ph.D. in Oceanography (Marine Chemistry) with research focus on the environmental fate of organic micro-pollutants. Environmental scientist within Pfizer Worldwide R&D for 5 years, with major responsibilities including the preparation of Environmental Risk Assessments and monitoring GLP studies. Active member of (b) (6)

The undersigned states that (1) the action requested qualifies for a categorical exclusion and meets categorical exclusion criteria 21 CFR 25.31 (c), and (2) to Pfizer-BioNTech's knowledge, no extraordinary circumstances exist.

(b) (6) PhD

Principal Scientist  
Environmental Sciences  
Pharmacokinetics, Dynamics and Metabolism  
Pfizer Worldwide Research and Development

(b) (6)

Signature

15 March 2021

Date

090177e19684b473\Approved\Approved On: 15-Mar-2021 12:52 (GMT)