

**ENVIRONMENTAL ASSESSMENT**

**COMIRNATY®**

**sBLA# 125742/45**

Vaccine for the prevention of COVID-19 disease caused by  
SARS-CoV-2 virus in patients 12-15 years of age

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

Pfizer-BioNTech claims 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 significantly alter the concentration or distribution of the substance, its metabolites or degradation products in the environment. The active ingredient is recognized as naturally occurring substance, Pfizer-BioNTech claims that to the best of our knowledge no extraordinary circumstances exist.

Preparer:

(b) (6) Senior Principal Scientist, Environmental Sciences, Pharmacokinetics, Dynamics and Metabolism, Pfizer Worldwide Research and Development. BS in Chemistry, MBA, Certified Industrial Hygienist with (b) (6) years experience in EH&S, including 23 years with Pfizer Inc.

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 knowledge, no extraordinary circumstance exist.

(b) (6)

Pfizer Worldwide Research and Development

26 January 2022

**Date**

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**Curriculum Vitae of the Expert**

(b) (6)  
Pfizer Worldwide R&D  
Groton, CT 06340

(b) (6)

**EDUCATION**

M.B.A. Masters in Business Administration,  
Professional Certificate in Industrial Hygiene  
(b) (6)  
B.S. Chemistry, (b) (6)

**EMPLOYMENT HISTORY**

1998–present Pfizer Worldwide Research & Development.  
Title: Senior Principal Scientist  
Pharmacokinetics, Dynamics and Metabolism  
(b) (6)  
Environmental Hygiene Associate

**RELEVANT EXPERIENCE**

Certified industrial hygienist with (b) (6) years of experience in environmental, health and safety; including 23 years in the pharmaceutical industry. Major responsibilities within Pfizer Worldwide R&D include worker safety, worldwide chemical registration, preparation of Environmental Risk Assessments. Lead in environmental toxicity and bioconcentration R&D with extensive experience in ERA regulatory documentation, data analyses, outsourcing and monitoring GLP studies. Active in (b) (6) activities.

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