

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 2024
See PRA Statement on last page.**TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE**1. Date Submitted
09/01/2021

2. Application Information

Single product Multiple products

For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.

Application Type: BLA

Application Number: 125324 /

NOTE: Form FDA 2253 is required by law. Reports are required for approved NDAs, ANDAs (21 CFR 314.81), and BLAs (601.12(f)(4))

3. Proprietary Name

Prevnar 13

4. Established Name

Pneumococcal 13-valent Conjugate Vaccine

Product Code No.: DR07

5. Package Insert Date and ID Number
(Latest final printed labeling)

07/19 LAB-0469-18.0

6. Manufacturer Name

Wyeth - a wholly-owned subsidiary of Pfizer Inc.

License No. (Biologics): 03

7. Advertisement / Promotional Labeling Materials

a. Please check only one: Professional Consumer

Material Type (use FDA codes) b.	Dissemination/ Publication Date c.	Material ID Code d.	Material Description e.	
www-website	09/01/2021	PP-PNA-USA-4653	Prevnar 13 ID Week 2021 Pfizer Platform	Delete Row

To delete a row, click the "Delete Row" button for that row (or press the enter key if you've tabbed into the button). You cannot delete the last remaining row.

Add New Row

f. Comments

Prevnar 20 tile presented on page 6 was submitted as part of a subpart E submission under job code PP-PNR-USA-0049.

PP-PNA-USA-4653 will be used with PP-CVV-USA-0357 filed 08/26/2021, PP-PNA-USA-4566 filed 08/30/2021, PP-PNP-USA-2059 filed 07/13/2021.

8. Applicant's (or Agent's) Return Address

Address 1 (Street address, P.O. box, company name c/o)

235 East 42nd Street, Regulatory Affairs, Wyeth

Address 2 (Apartment, suite, unit, building, floor, etc.)

a wholly-owned subsidiary of Pfizer Inc.

City

New York

State/Province/Region

New York

Country

US

ZIP or Postal Code

10017

9. Responsible Official's (or Agent's)

a. Telephone Number (Include area code)

(484) 865-5035

b. FAX Number (Include area code)

(845) 474-3500

c. Email Address

Donna.Boyce@pfizer.com

10. Typed Name and Title of Responsible Official or Agent Donna Boyce M.S., Senior Vice President, Global Regulatory Affairs, Global Product Development	11. Signature of Responsible Official or Agent <div style="display: flex; align-items: center;"> <div style="margin-right: 10px;">(b) (6)</div> <div style="font-size: 8px;"> Digitally signed by (b) (6) DN: o=Pfizer Inc, (b) (6) Reason: I am signing on behalf of Donna Boyce Location: (b) (6) Date: 2021.09.01 10:05:08.00 </div> <div style="margin-left: 10px; border: 1px solid black; padding: 2px 5px; background-color: yellow;">Sign</div> </div>	12. Date 09/01/2021
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13. For CBER Products Only (Check one) <div style="display: flex; justify-content: center; gap: 20px;"> Draft ✕ Final </div>

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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