

Food and Drug Administration

Package Inserts & FDA Product Approvals

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[Yellow fever](#)
[Zoster \(shingles\)](#)

Product Approval - Adenovirus

[Adenovirus Package Insert](#)

Barr Labs Inc.

[Adenovirus Product Approval](#)

Product Approval - Anthrax

[BioThrax Package Insert](#)

Emergent BioSolutions

[BioThrax Product Approval](#)

Product Approval - BCG Vaccine (tuberculosis)

[BCG Package Insert](#)

Organon Teknica (Merck)

[BCG Product Approval](#)

Product Approval - Cholera

[Vaxchora Package Insert](#)

Emergent BioSolutions

[Vaxchora Product Approval](#)

Product Approval - FDA Approval and Emergency Use Authorization (EUA) – COVID-19

[Comirnaty Package Insert](#)

Pfizer-BioNTech

[Comirnaty Product Approval](#)

[EUA Full Prescribing Information](#)

Pfizer-BioNTech

[Letter of Authorization](#)

[Fact Sheet for Healthcare Providers](#)

[Fact Sheets for Patients](#)

[EUA Full Prescribing Information](#)

Janssen (Johnson and Johnson)

[Letter of Authorization](#)

[Fact Sheet for Healthcare Providers](#)

[Fact Sheet for Patients](#)

[Spikevax Package Insert](#)

Moderna

[Spikevax Product Approval](#)

[EUA Full Prescribing Information](#)

Moderna

[Letter of Authorization](#)

[Fact Sheet for Healthcare Providers](#)

[Fact Sheets for Patients](#)

[EUA Full Prescribing Information](#)

Novavax, Inc

[Letter of Authorization](#)

[Fact Sheet for Healthcare Providers](#)

[Fact Sheets for Patients](#)

Product Approval - Dengue

[Dengvaxia Package Insert](#)

Sanofi U.S.

[Dengvaxia Product Approval](#)

Product Approval - DT

[DT \(generic\) Package Insert](#)

Sanofi U.S.

[DT \(generic\) Product Approval](#)

Product Approval - DTaP

[Daptacel Package Insert](#)
Sanofi U.S.
[Daptacel Product Approval](#)

[Infanrix Package Insert](#)
GSK
[Infanrix Product Approval](#)

[Kinrix Package Insert](#)
GSK
[Kinrix Product Approval](#)

[Pediarix Package Insert](#)
GSK
[Pediarix Product Approval](#)

Product Approval - Ebola virus disease (EVD)

[Ervebo Package Insert](#)
Merck & Co, Inc.
[Ervebo Product Approval](#)

Product Approval - *Haemophilus influenzae* type b

[ActHIB Package Insert](#)
Sanofi U.S.
[ActHIB Product Approval](#)

[Hiberix Package Insert](#)
GSK
[Hiberix Product Approval](#)

[PedvaxHIB Package Insert](#)
Merck & Co., Inc.
[PedvaxHIB Product Approval](#)

Product Approval - Hepatitis A

[Havrix Package Insert](#)
GSK
[Havrix Product Approval](#)

[Twinrix Package Insert](#)
GSK
[Twinrix Product Approval](#)

Product Approval - Hepatitis B

[Engerix-B Package Insert](#)
GSK
[Engerix-B Product Approval](#)

[Heplisav-B Package Insert](#)
Dynavax Technologies
[Heplisav-B Product Approval](#)

[Pediarix Package Insert](#)
GSK
[Pediarix Product Approval](#)

[PreHevbrio Package Insert](#)
VBI Vaccines Inc.
[PreHevbrio Product Approval](#)

Product Approval - Human papillomavirus (HPV)

[Gardasil 9 Package Insert](#)
Merck & Co., Inc.
[Gardasil 9 Product Approval](#)

[Pentacel Package Insert](#)
Sanofi U.S.
[Pentacel Product Approval](#)

[Quadracel Package Insert](#)
Sanofi U.S.
[Quadracel Product Approval](#)

[Vaxelis Package Insert](#)
Sanofi U.S.
[Vaxelis Product Approval](#)

[Pentacel Package Insert](#)
Sanofi U.S.
[Pentacel Product Approval](#)

[Vaxelis Package Insert](#)
Sanofi U.S.
[Vaxelis Product Approval](#)

[Vaqta Package Insert](#)
Merck & Co., Inc.
[Vaqta Product Approval](#)

[Recombivax HB Package Insert](#)
Merck & Co., Inc.
[Recombivax HB Product Approval](#)

[Twinrix Package Insert](#)
GSK
[Twinrix Product Approval](#)

[Vaxelis Package Insert](#)
Sanofi U.S.
[Vaxelis Product Approval](#)

Product Approval - Influenza

Afluria Quadrivalent Package Insert

Seqirus

Afluria Quadrivalent Product Approval (injectable)

Fluad Quadrivalent Package Insert

Seqirus

Fluad Quadrivalent Product Approval (injectable)

Fluarix Quadrivalent Package Insert

GSK

Fluarix Quadrivalent Product Approval (injectable)

Flublok Quadrivalent Package Insert

Protein Sciences Corporation

Flublok Quadrivalent Product Approval (injectable)

Flucelvax Quadrivalent Package Insert

Seqirus

Flucelvax Quadrivalent Product Approval (injectable)

FluLaval Quadrivalent Package Insert

ID Biomedical Corporation

FluLaval Quadrivalent Product Approval (injectable)

FluMist Quadrivalent Package Insert

MedImmune, Inc.

FluMist Quadrivalent Product Approval (intranasal)

Fluzone High Dose Quadrivalent Package Insert

Sanofi U.S.

Fluzone High Dose Quadrivalent Product Approval (injectable)

Fluzone Quadrivalent Package Insert

Sanofi U.S.

Fluzone Quadrivalent Product Approval (injectable)

Product Approval - Japanese encephalitis

IXIARO Package Insert

Valneva

IXIARO Product Approval

Product Approval - Measles

MMR II Package Insert

Merck & Co., Inc.

MMR II Product Approval

Priorix Package Insert

GSK

Priorix Product Approval

ProQuad Package Insert

Merck & Co., Inc.

ProQuad Product Approval

Product Approval - Meningococcal ACWY

Menactra Package Insert

Sanofi U.S.

Menactra Product Approval

MenQuadfi Package Insert

Sanofi U.S.

MenQuadfi Product Approval

Menveo Package Insert

GSK

Menveo Product Approval

Product Approval - Meningococcal B

Bexsero Package Insert

GSK

Bexsero Product Approval

Trumenba Package Insert

Pfizer

Trumenba Product Approval

Product Approval - Mumps

MMR II Package Insert

Merck & Co.

MMR II Product Approval

Priorix Package Insert

GSK

Priorix Product Approval

ProQuad Package Insert

Merck & Co.

ProQuad Product Approval

Product Approval - Pneumococcal (PCV)

Prevnar 13 Package Insert

Pfizer

Pprevnar 13 Product Approval

Vaxneuvance (PCV15) Package Insert

Merck & Co, Inc.

Vaxneuvance (PCV15) Product Approval

[Pevnar 20 Package Insert](#)

Pfizer

[Pevnar 20 Product Approval](#)

Product Approval - Pneumococcal (PPSV)

[Pneumovax 23 Package Insert](#)

Merck & Co., Inc.

[Pneumovax 23 Product Approval](#)

Product Approval - Polio (IPV)

[IPOL Package Insert](#)

Sanofi U.S.

[IPOL Product Approval](#)

[Kinrix Package Insert](#)

GSK

[Kinrix Product Approval](#)

[Pediarix Package Insert](#)

GSK

[Pediarix Product Approval](#)

Product Approval - Rabies

[Imovax Package Insert](#)

Sanofi U.S.

[Imovax Product Approval](#)

Product Approval - Rotavirus

[Rotarix Package Insert](#)

GSK

[Rotarix Product Approval](#)

Product Approval - Rubella

[MMR II Package Insert](#)

Merck & Co., Inc.

[MMR II Product Approval](#)

[Priorix Package Insert](#)

GSK

[Priorix Product Approval](#)

Product Approval - Smallpox and Monkeypox

[ACAM2000 Package Insert](#)

Emergent Biosolutions

[ACAM2000 Product Approval - \(smallpox only\)](#)

[Pentacel Package Insert](#)

Sanofi U.S.

[Pentacel Product Approval](#)

[Quadracel Package Insert](#)

Sanofi U.S.

[Quadracel Product Approval](#)

[Vaxelis Package Insert](#)

Sanofi U.S.

[Vaxelis Product Approval](#)

[RabAvert Package Insert](#)

Bavarian Nordic

[RabAvert Product Approval](#)

[RotaTeq Package Insert](#)

Merck & Co., Inc.

[RotaTeq Product Approval](#)

[ProQuad Package Insert](#)

Merck & Co., Inc.

[ProQuad Product Approval](#)

[Jynneos Package Insert](#)

Bavarian Nordic A/S

[Jynneos Product Approval](#)

[EUA Full Prescribing Information](#)

Jynneos

[Letter of Authorization](#)

[Fact Sheet for Healthcare Providers](#)

[Fact Sheet for Patients](#)

Product Approval - Tetanus (Td)

[Td \(generic\) Package Insert](#)

Mass. Biological Lab

[Td \(generic\) Product Approval](#)

[Tenivac Package Insert](#)

Sanofi U.S.

[Tenivac Product Approval](#)

Product Approval - Tetanus (Tdap)

[Adacel Package Insert](#)

Sanofi U.S.

[Adacel Product Approval](#)

[Boostrix Package Insert](#)

GSK

[Boostrix Product Approval](#)

Product Approval – Tick-borne encephalitis

[Ticovac Package Insert](#)

Pfizer

[Ticovac Product Approval](#)

Product Approval - Typhoid

[Typhim Vi Package Insert](#)

Sanofi U.S.

[Typhim Vi Product Approval](#)

[Vivotif Package Insert](#)

Emergent BioSolutions

[Vivotif Product Approval](#)

Product Approval - Varicella (chickenpox)

[Varivax Package Insert](#)

Merck & Co., Inc.

[Varivax Product Approval](#)

[ProQuad Package Insert](#)

Merck & Co., Inc.

[ProQuad Product Approval](#)

Product Approval - Yellow Fever

[YF-Vax Package Insert](#)

Sanofi U.S.

[YF-Vax Product Approval](#)

Product Approval - Zoster (shingles)

[Shingrix Package Insert](#)

GSK

[Shingrix Product Approval](#)

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