FDA authorizes COVID-19 vaccine for adolescents ages 12-15
by Melissa Jenco, News Content Editor


Adolescents moved a step closer to being able to receive a COVID-19 vaccine after officials on Monday approved Pfizer-BioNTech's vaccine for those ages 12-15 years.

Trials showed the Pfizer-BioNTech vaccine was 100% effective and presented no serious safety concerns in adolescents, leading the Food and Drug Administration (FDA) to grant emergency use authorization (EUA). The vaccine previously was authorized for people ages 16 and older.

"Today's action allows for a younger population to be protected from COVID-19, bringing us closer to returning to a sense of normalcy and to ending the pandemic," Acting FDA Commissioner Janet Woodcock, M.D., said in a news release. "Parents and guardians can rest assured that the agency undertook a rigorous and thorough review of all available data, as we have with all of our COVID-19 vaccine emergency use authorizations."

Pfizer and BioNTech conducted trials in 2,260 adolescents with half randomized to receive the vaccine and half to receive a placebo. Participants were followed for two months.

Among 1,005 vaccine recipients, there were no cases of COVID-19, while 16 were reported among 978 placebo recipients. An immunogenicity analysis in 190 participants also showed their response was just as good as the response for those ages 16-25 years.

The most common side effects in adolescents were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain, consistent with trials in older teens and adults.

Since March 2020, about 1.5 million adolescents ages 11-17 years have been diagnosed with COVID-19, according to Centers for Disease Control and Prevention (CDC) data. The pandemic also has taken a toll on children's mental and emotional health, social well-being and their educational experience.

AAP President Lee Savio Beers, M.D., FAAP, applauded the FDA’s action, calling it a "critically important step in bringing life-saving vaccines to children and adolescents."
"Our youngest generations have shouldered heavy burdens over the past year, and the vaccine is a hopeful sign that they will be able to begin to experience all the activities that are so important for their health and development," Dr. Beers said in a statement.

The CDC's Advisory Committee on Immunization Practices will meet on May 12 to discuss additional guidance on use of the vaccine for adolescents, and the AAP also will make official recommendations.

Health officials plan to focus on making vaccines available through pediatricians and family physicians. Dr. Beers said pediatricians stand ready to assist. The AAP recently released recommendations on implementing COVID-19 vaccination in pediatric practices (see resources).

The vaccine will be given to adolescents in two doses three weeks apart, the same as for adults. It should not be given to anyone with a history of severe allergic reaction to any component of the vaccine.

Several vaccine manufacturers also are conducting trials in younger children. Pfizer leaders recently said they expect to request an EUA in September to vaccinate children ages 2-11 followed by authorization for ages 6 months to 2 years in the fourth quarter.

Resources

- Fact sheet for health care providers
- Fact sheet for vaccine recipients and caregivers
- The AAP will hold a town hall to discuss adolescent vaccination at 8 p.m. Eastern on May 13. Register at https://zoom.us/webinar/register/WN_61dBaJUFTeKmqLycNnWwBg
- AAP guidance on COVID-19 vaccines for children
- AAP News story "AAP develops coding, billing guidance for COVID-19 vaccine services"
- Information for parents from HealthyChildren.org on COVID-19 vaccines for children and adolescents