



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE  
Thomas Farley, MD, MPH  
*Commissioner*

Bureau of Immunization  
42-09 28<sup>th</sup> Street  
5<sup>th</sup> floor– CN21  
Long Island City, NY 11101

July 14, 2001

Dear Colleague:

Please see the announcement below from the U.S. Food and Drug Administration that Tdap vaccine is now licensed for use in persons 65 and older. The Advisory Committee on Immunization Practices (ACIP) had previously recommended that Tdap be given to health care workers and caregivers of infants who are aged 65 and older. This is no longer an off label indication.

In addition to a routine adolescent Tdap recommendation, the ACIP has also recommended a single dose of Tdap (if not previously given) for the following adults:

- All adults who are due for their every 10 year Td booster;
- All pregnant women late in the second trimester or third trimester of pregnancy;
- All women in the immediate post-partum period (breast feeding is not a contraindication);
- All close contacts of children younger than 12 months of age;
- All health care workers;
- For wound care if a tetanus-containing vaccine is indicated.

For additional information about the use of Tdap, please see <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm#tdap>

Thank you.

## **FDA NEWS RELEASE**

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm262390.htm>

**For Immediate Release:** July 8, 2011

**Consumer Inquiries:** 888-INFO-FDA

### **FDA approves Boostrix to prevent tetanus, diphtheria, and pertussis in older people**

The U.S. Food and Drug Administration today approved Boostrix vaccine to prevent tetanus, diphtheria, and pertussis (whooping cough) in people ages 65 and older.

Currently, there are vaccines approved for the prevention of tetanus and diphtheria that can be used in adults 65 and older. Boostrix, which is given as a single-dose booster shot, is the first vaccine approved to prevent all three diseases in older people.

Tetanus can cause paralysis and is caused by bacteria that live in soil, dust, and manure. The bacteria usually enter the body through a deep cut. Diphtheria is a serious bacterial infection that usually causes a bad sore throat, swollen glands, fever, and chills. If not properly diagnosed and treated, serious complications such as heart failure or paralysis can result. Pertussis is a disease that causes uncontrollable coughing; the infected person makes a noise when they breathe after coughing that sounds like “whoop.” The incidence of pertussis disease in the United States has been increasing since 2007, with large local outbreaks occurring in 2010 in California, Michigan, and Ohio. “Pertussis is a highly contagious disease, and outbreaks have occurred among the elderly in nursing homes and hospitals,” said Karen Midthun, M.D., director of FDA's Center for Biologics Evaluation and Research. “With this approval, adults 65 and older now have the opportunity to receive a vaccine that prevents pertussis, as well as tetanus and diphtheria.”

The safety and effectiveness of Boostrix was based on a study of about 1,300 people ages 65 and older. To demonstrate its ability to protect against pertussis, the antibody levels among participants were measured and found comparable to the levels in infants who received a closely related vaccine that was shown to prevent pertussis. The antibody responses to the tetanus and diphtheria components were compared with a licensed tetanus and diphtheria vaccine, and were found comparable. The most common adverse reactions reported by the older adults after receiving Boostrix were headache, and fatigue and pain at the injection site.

Boostrix was originally approved on May 3, 2005, for use in adolescents ages 10 years through 18 years. It subsequently was approved in December 2008, to include adults 19 years through 64 years of age. Boostrix is manufactured by GlaxoSmithKline Biologicals, based in Rixensart, Belgium.

For more information:

[Boostrix Product Page](#)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.