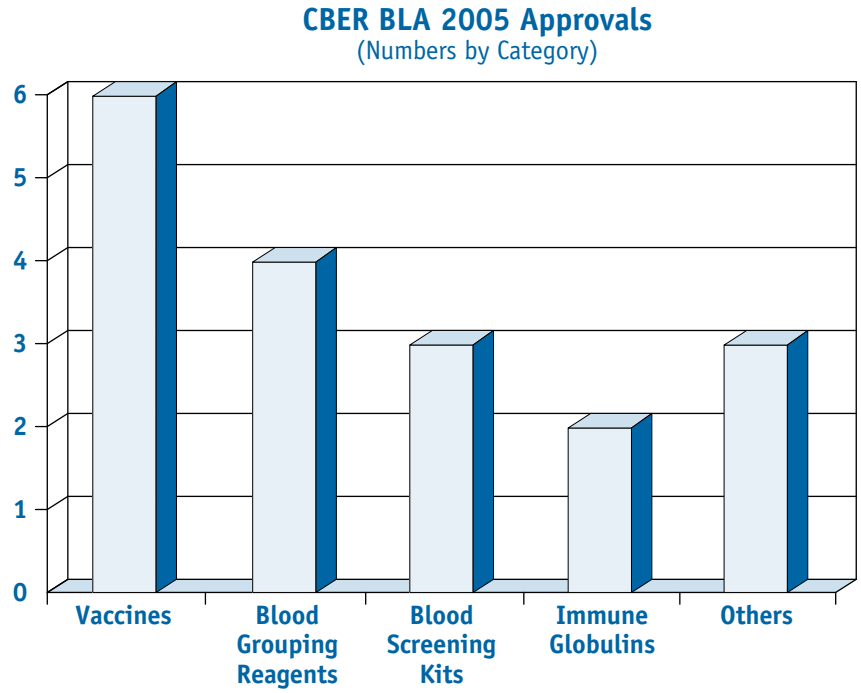
CBER: Oversees the safety and effectiveness of biological products, and contributes scientific expertise to support influenza preparedness

The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) oversees the safety and effectiveness of biological products, including vaccines, blood and blood components, human tissues, certain medical devices, and novel products such as cell, gene, and tissue-based therapies.

In 2005, in addition to evaluating new products, CBER made major efforts to ensure the supply of vaccine before the 2005–2006 flu season, advance the Critical Path initiative, strengthen the safety of tissues for transplantation, and prepare for a possible outbreak of pandemic influenza.

MAJOR PRODUCT APPROVALS

In 2005, CBER approved 18 biologics license applications (BLAs) (see graph). Six of the 2005 approvals were for vaccines, a category of products that is increasingly important because of the potential risks of pandemic influenza and bioterrorism.



MAJOR 2005 PRODUCT APPROVALS

- Fluarix, GlaxoSmithKline's (GSK's) influenza vaccine for immunization of adults ages 18 and older against influenza caused by virus types A and B. Fluarix, which was approved in just over three months, was the first vaccine to receive the FDA's accelerated approval.
- Two Vaccinia Immune Globulin Intravenous (VIGIV) products to treat certain rare complications of smallpox vaccination. Both products were granted priority review. Smallpox is believed to pose the greatest threat to public health from bioterrorism, along with anthrax, botulism, and plague.
- Procleix WNV Assay, the first test to screen blood, tissue, cell, and organ donors for West Nile virus. The test will help protect patients who receive blood and other donated products against West Nile infection. In the past, about 30 patients are believed to have acquired the virus from a blood transfusion, and nine of them died.
- Two new combination vaccines to prevent whooping cough: Boostrix (GSK) for adolescents ages 10 to 18, and Adacel for ages 11 to 64. Whooping cough is a highly communicable and potentially serious illness in both adolescents and adults.

OTHER SIGNIFICANT ACTIONS

Chiron remediation: Throughout 2005, CBER cooperated closely with the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to ensure correction of sterility failures that had caused the MHRA to suspend the license for vaccine production by Chiron at its British facility. This facility produces influenza vaccine for the United States. Both the FDA and the MHRA provided extensive input on Chiron's remediation plan, and CBER's specialists and their MHRA colleagues inspected the affected facility. The joint efforts resulted in the release and delivery of Chiron's Fluvirin influenza vaccine to the United States for the 2005–2006 influenza season.

Critical Path initiative: CBER made several contributions to this FDA initiative for modernizing the development of medical products. For example, the center developed a novel mouse model that was adopted by the National Institutes of Health and industry, and was used in the development of VIGIV. CBER also developed materials for the test for the West Nile virus, and provided guidance for its pathway to approval. This assay prevented the use of more than 1,600 units of infected blood.

New tissue rules: Another major CBER priority in 2005 was the implementation of new regulations to prevent the transmission of diseases through transplanted human cells, tissues, and cellular and tissue-based products (HCT/Ps). Among other measures, CBER facilitated the registration of more than 2,000 HCT/P establishments, developed and implemented a new HCT/P inspection program, provided guidance for reporting of HCT/P adverse reactions, and formed a team to coordinate and facilitate FDA responses to such events.

PANDEMIC INFLUENZA PREPAREDNESS

CBER's scientific expertise is crucial for pandemic influenza preparedness. In 2005, CBER advanced this vital program researching pathways to speed vaccine manufacturing and availability, increasing the number of vaccine manufacturers and their capacity, and addressing needs such as creation of pandemic strain libraries, antisera, and improved assays and testing.