FDA's Center on the Front Line of the Biomedical Frontier

The nation's more than $40 billion annual investment in **biomolecular research** is fueling a deluge of promising new medications that will eventually land at the FDA's door, seeking approval to enter the market. For many of the most exotic treatments—from cellular replacement therapies to animal organ transplants—the gatekeeper is the **Center for Biologics Evaluation and Research** (CBER).

CBER regulates biological products for disease prevention and treatment that are inherently more complex than chemically synthesized pharmaceuticals, including:

- **Blood and blood products,** such as plasma, blood-derived proteins including clotting factors for hemophilia, tests used to screen blood donors and devices used to make blood products.
- **Vaccines and allergenic products.**
- **Protein-based drugs,** such as monoclonal antibodies and cytokines that stimulate the immune system to fight cancer, and enzyme therapies that stop heart attacks.

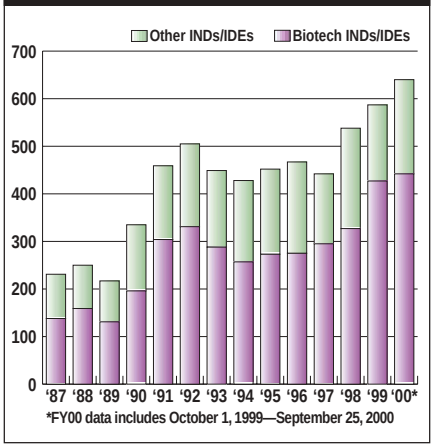
These and other biological products have the potential to provide immense public health benefits, and they are being developed at an annual rate that has increased from 350 in 1990 to more than 650 in 2000.

In addition, CBER's scientists are prepared to evaluate the safety and effectiveness of products that will result from the most complex and exciting areas of biomedical research, including:

- **Human gene therapy** designed to alleviate human diseases by transferring normal versions of genes into target cells.
- **Xenotransplantation,** the technique in which organs, tissues or cells from animals such as pigs are transplanted into patients.
- **Cellular and tissue transplants,** including stem cell therapy, which offer the promise of new therapeutic treatments, including restoring damaged tissue.
- **Transgenic plants and animals** whose products will result in new biotech vaccines and therapeutics.
- **Genomics, proteomics and bioinformatics**, techniques that will lead the way for new biological product discovery and patient management.
- **Variant CJD and BSE.** Evaluation of methods for testing and removal from blood products of infectious particles that cause the human illness associated with BSE or "mad cow disease."
- **Nucleic Acid Testing,** methods to detect known pathogens with ever greater sensitivity and to identify emerging variants of these agents.
- **New vaccines and new vaccine technologies.** Vaccines against diseases like AIDS, TB, malaria, antibiotic resistant infections and chronic illnesses are beginning to show promise.

For more information, please call CBER at 1-800-835-4709 or 301-827-2000, or visit the FDA Web site at *www.fda.gov/cber.*

CBER Biotech INDs/IDEs Received Fiscal Year 87-FY 00



The rising number of investigational new biotech drug and device applications indicates an increasing number of new products to be reviewed by CBER in the coming years.

Countering Bioterrorism

CBER plays an integral role in several initiatives to protect the Nation against bioterrorism. The center is helping to advance the development and licensing of products to diagnose, treat, or prevent outbreaks from exposure to bioterrorist pathogens by entering the process at an early stage and helping the products to rapidly meet the regulatory requirements. The center also is developing procedures and protocols to make possible the safe use of promising experimental products when there is no approved medication for the treatment of victims of terrorism.

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