The regulatory responsibility, review and continuing oversight for many biologic therapeutic products has been transferred from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER).

The information is now located at http://www.fda.gov/cder/biologics/default.htm

Biological Therapeutic Products

- Approval Information (Labels and Reviews)
- Letters to Industry, Healthcare Providers, and Clinical Investigators
- Prescription Drug User Fee Act (PDUFA) Billable Products
- Recalls and Withdrawals
- Research Divisions and Investigators
- Talk Papers
- Safety Information
- Violative Advertising and Promotional Labeling Letters

On October 1, 2003, FDA transferred certain product oversight responsibilities from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This consolidation provides greater opportunities to further develop and coordinate scientific and regulatory activities between CBER and CDER, leading to a more efficient, effective, and consistent review program for human drugs and biologics. FDA believes that as more drug and biological products are developed for a broader range of illnesses, such interaction is necessary for both efficient and consistent agency action. Under the new structure, the biologic products transferred to CDER will continue to be regulated as licensed biologics.

To see which product classes have been transferred and which will remain at CBER, please refer to Transfer of Therapeutic Products to the Center for Drug Evaluation and Research.

The staff that was formally with CBER as the Office of Therapeutics Research and Review (OTRR) will maintain responsibility for the therapeutic biologics through two new Offices that have been formed in CDER. The following table lists the new CDER Offices and Divisions established to review therapeutic biologic products.

CDER Office of New Drugs: Office of Drug Evaluation VI **Karen Weiss, MD, Director**	**CDER Office of Pharmaceutical Science: Office of Biotechnology Products** **Yuan-yuan Chiu, PhD, Acting Director**
Division of Therapeutic Oncology Products (DTBOP) Patricia Keegan, MD, director	Division of Monoclonal Antibodies (DMA) Keith O. Webber, PhD, director Steven Kozlowski, MD, acting deputy director
Division of Therapeutic Biological Internal Medicine Products (DTBIMP) Marc Walton, MD, director	Division of Therapeutic Proteins (DTP) Amy Rosenberg, MD, director Barry W. Cherney, PhD, deputy director
Division of Review Management and Policy (DRMP) Earl S. Dye, PhD, acting director	

The therapeutic biological products now under CDER's review include:

- Monoclonal antibodies for in-vivo use
- Cytokines, growth factors, enzymes, immunomodulators; and thrombolytics
- Proteins intended for therapeutic use that are extracted from animals or microorganisms, including recombinant versions of these products (except clotting factors)
- Other non-vaccine therapeutic immunotherapies

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