Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research

On June 30, 2003, FDA transferred some of the therapeutic biological products that had been reviewed and regulated by the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). CDER now has regulatory responsibility, including premarket review and continuing oversight, over the transferred products. In regulating the products assigned to them, CBER and CDER will consult with each other regularly and whenever necessary. On October 1, 2003, the staff comprising CBER's Office of Therapeutics Research and Review also transferred to CDER.

The lists below identify categories of biological products transferred from CBER to CDER, and categories of biological products remaining in CBER. Please note that the CBER list contains only a portion of the products CBER currently regulates; this list contains products that are closely related in chemical structure to products that transferred to CDER, e.g. therapeutic proteins and polysaccharides. Products are included on the CBER list as a means of clarifying the products that transferred and those that did not.

Categories of Biological Products Transferred to CDER

- Monoclonal antibodies for in vivo use.
- Proteins intended for therapeutic use, including cytokines (e.g. interferons), enzymes (e.g. thrombolytics), and other novel proteins, except for those that are specifically assigned to CBER (e.g., vaccines and blood products). This category includes therapeutic proteins derived from plants, animals, or microorganisms, and recombinant versions of these products.
- Immunomodulators: proteins or peptides that are not antigen specific (e.g., cytokines, growth factors, chemokines, etc.) that are intended to treat disease by inhibiting or modifying a pre-exisiting immune response; and proteins or peptides intended to act in antigen-specific fashion to treat or prevent autoimmune diseases by inhibiting or modifying pre-existing immune responses.
- Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of cells in vivo.[1] This category includes growth factors, cytokines, and monoclonal antibodies, as well as non-biological agents, administered as mobilizing agents for their direct therapeutic effect on the recipient, as well as growth factors, cytokines, and monoclonal antibodies administered for the purpose of subsequently harvesting the mobilized, stimulated, decreased or otherwise altered cells for use in a human cellular or tissue-based product (HCT/P).

Categories of Biological Products Remaining in CBER

- Cellular products, including products composed of human, bacterial or animal cells (such as pancreatic islet cells for transplantation), or from physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines).
- Gene therapy products. Human gene therapy/gene transfer is the administration of nucleic acids, viruses, or genetically engineered microorganisms that mediate their effect by transcription and/or translation of the transferred genetic material, and/or by integrating into the host genome. Cells may be modified in these ways ex vivo for subsequent administration to the recipient, or altered in vivo by gene therapy products administered directly to the recipient.
- Vaccines and vaccine-associated products: products, regardless of their composition or method of manufacture, intended to induce or enhance a specific immune response to

prevent or treat a disease or condition, or to enhance the activity of other therapeutic interventions.

- Allergenic extracts used for the diagnosis and treatment of allergic diseases and allergen patch tests.
- Antitoxins, antivenins, and venoms
- Blood, blood components, plasma derived products (for example, albumin, immunoglobulins, clotting factors, fibrin sealants, proteinase inhibitors), including recombinant and transgenic versions of plasma derivatives, (for example clotting factors), blood substitutes, plasma volume expanders, human or animal polyclonal antibody preparations including radiolabeled or conjugated forms, and certain fibrinolytics such as plasma-derived plasmin, and red cell reagents.
- Human cells, tissues and cellular and tissue-based products (HCT/P's). This category includes HCT/P's containing cells that have been harvested following in vivo administration of a CDER-regulated growth factor, cytokine, or monoclonal antibody,[2] as well as HCT/P's requiring ex vivo manipulation.

Combination Products

The lists above contain some combination products comprised of a biological product component with a device and/or drug component, though such products are not specifically identified. Combination products are assigned to a Center for review and regulation in accordance with the products' primary mode of action.[3] When a product's primary mode of action is attributable to a type of biological product assigned to CDER, the product will be assigned to CDER. Similarly, when a product's primary mode of action is attributable to a type of biological product assigned to CBER, the product will be assigned to CBER. For further information about combination products, see www.fda.gov/oc/combination, or contact the Office of Combination Products at 301-427-1934, or combination@fda.gov.

Further Information

Questions about the assignment of specific products to CBER or CDER should be directed to the center jurisdiction officers at:

CDER Ombudsman 301-594-5480

CBER Ombudsman 301-827-0379

Footnotes

[1]CBER reviews and regulates some products other than growth factors, cytokines, and monoclonal antibodies that are mobilizing agents in that they are administered in vivo for mobilizing, stimulating, decreasing or otherwise altering the production or function of cells or tissues that are subsequently harvested for use in an HCT/P. The mobilizing agents and other cell manipulating agents reviewed and regulated by CBER also fall into one of the categories of products currently assigned to CBER (e.g., a vaccine or gene therapy).

[2]The most efficient way to investigate an HCT/P developed from cells that have been harvested following in vivo administration of a growth factor, cytokine, or monoclonal antibody would ordinarily be to first investigate the safety and activity of the growth factor, cytokine, or monoclonal antibody in mobilizing, stimulating, decreasing or otherwise altering cells in vivo, and then to reference this information in a subsequent application to CBER for the HCT/P. The Center

jurisdiction officers listed below are available to discuss the various options and appropriate regulatory approaches.

[3] See 21 U.S.C. § 353(g), section 503(g) of the Federal Food, Drug, and Cosmetic Act.