

TABLE 9.2 (Continued)

Approved Products Transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research

| Product Name | Proprietary Name | Applicant Name |
|--|-----------------------------------|----------------------------|
| Peginterferon alpha-2b | Polyethylene glycol (PEG)-Intron® | Schering Corp. |
| Rasburicase | Elitek® | Sanofi-Synthelabo, Inc. |
| Reteplase | Retavase® | Centocor, Inc. |
| Rituximab | Rituxan® | Genentech, Inc. |
| Rituximab formulated bulk | | IDEC Pharmaceuticals Corp. |
| Sargramostim | Leukine® | Berlex Laboratories, Inc. |
| Satumomab concentrate | | LONZA Biologics PLC |
| Satumomab pendetide | OncoScint CR/OV® | Cytogen Corp. |
| Streptokinase | Streptase® | Aventis Behring GmbH |
| Tenecteplase | TNKase® | Genentech, Inc. |
| Tositumomab and iodine I 131 tositumomab | Bexxar® | Corixa Corp. |
| Trastuzumab | Herceptin® | Genentech, Inc. |
| Urokinase | Abbokinase® | Abbott Laboratories |

The categories of therapeutic biological products transferred to CDER (2) are as follows:

- Monoclonal antibodies (MAbs) 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 (nonvaccine and nonallergenic products intended to treat disease by inhibiting or modifying a pre-existing immune response).
- Growth factors, cytokines, and MAbs intended to mobilize, stimulate, decrease, or otherwise alter the production of hematopoietic cells in vivo.

The categories of therapeutic biological products that remain in the CBER are as follows:

- Cellular products, including products composed of human, bacterial, or animal cells (such as pancreatic islet cells for transplantation), or physical parts of those cells (such as whole cells, cell fragments, and 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