Table 16.1 EXAMPLES OF OFFICIAL BIOLOGIC PRODUCTS (Continued)

BIOLOGIC PRODUCT	NATURE OF CONTENTS	ROUTE[a]	USE
Candida albicans skin test antigen	From culture filtrate, cells of two strains of *C. albicans*	ID	Detects reduced cellular hypersensitivity, DTH; assesses diminished cellular immunity in HIV
Histoplasmin, USP	Standardized culture filtrates of fungus *Histoplasma capsulatum* grown on liquid synthetic medium	ID	Diagnostic aid (histoplasmosis)
Plasma Protein Fraction, USP	Blood plasma of adult human donors; contains ~ 5% protein, ~ 88% normal human albumin;, 12% *alpha* and *beta* globulins	IV	Blood volume expansion
Tuberculin, USP	Solution of concentrated soluble products of MTB. Old tuberculin, soluble partially purified product of MTB in special liquid medium free of protein (purified protein derivative)	ID	Diagnostic aid (tuberculosis)

[a]The doses to be administered and the schedule of doses vary widely with the patient's age, exposure, previous record of immunizations, and so on.
BCG, bacille Calmette-Guérin; IM, intramuscular; SQ, subcutaneous; HBsAg, hepatitis B surface antigen; HDCV, human diploid cell vaccine; RDCV, rhesus diploid cell vaccine; ID, intradermal; ITP, idiopathic thrombocytopenic purpura; CLL, chronic lymphocytic leukemia; IgG, immunoglobulin gamma; DTH, delayed-type hypersensitivity; MTB, *Mycobacterium tuberculosis*.

side effects. Liposomal delivery has decreased side effects while enhancing the vaccine's effectiveness.

Itching, erythema, pain, and tenderness around the injection site occur with subcutaneous, IM, and intradermal administration. Vaccines that contain adjuvants (e.g., BCG) can cause these adverse effects in addition to induration and ulceration at the site. Low-grade fever, myalgia, and arthralgia have occurred in patients who received a BCG-containing biologic product.

These adverse effects are controlled with the use of over-the-counter analgesic agents. However, before these are used, the patient's drug history should be obtained to ensure that the use of an analgesic is permissible given a patient's health status and other drug therapy.

The foremost adverse effect of concern with immunization is hypersensitivity, most notably anaphylaxis, ranging from pruritus or urticaria to bronchospasm, respiratory distress, laryngeal edema, circulatory collapse, and death. Life-threatening anaphylaxis is a rarity but quite possible. The risk of an anaphylactic reaction is in the range of one for every 600,000 to 6.4 million doses of vaccine distributed (7).

The immunopathologic classification of allergic drug reactions places anaphylactic reactions in type I. In this situation, initial exposure to an antigen results in production of specific IgE antibodies. Upon reexposure, antigen reacts with antibodies bound to the surface of mast cells or basophils, causing the release of histamine and other mediators. Several weeks are required after initial exposure to antigen and sensitization before an anaphylactic reaction can occur. Once sensitized, however, the patient can demonstrate an attack within minutes of reexposure to small amounts of the drug administered by any route.

Because of the rare nature of anaphylactic reactions, it is difficult to determine whether the patient is allergic to the proteins that make up the active antigenic portion of the vaccine or to the excipients (e.g., neomycin, gelatin, aluminum gels). Several viruses that constitute vaccines are grown in animate media, including embryonic egg and cell