FDA Warns Michigan Biologic Products Institute of Intention to Revoke Licenses

FDA issued a letter to the Michigan Biologic Products Institute (MBPI), Lansing, Michigan, on March 11, 1997, warning that the agency will initiate steps to revoke MBPI's establishment and product licenses unless immediate action is taken to correct deficiencies at the firm. MBPI is currently licensed to manufacture Diphtheria Toxoid Adsorbed, Tetanus Toxoid Adsorbed, Rabies Vaccine Adsorbed, Antihemophilic Factor (Human), Immune Globulin (Human), Albumin (Human), Anthrax Vaccine Adsorbed, Pertussis Vaccine Adsorbed, Diphtheria & Tetanus Toxoids Adsorbed, and Diphtheria & Tetanus Toxoids & Pertussis Vaccine Adsorbed. MBPI can remain open while it attempts to address the deficiencies cited by FDA.

An FDA inspection of MBPI conducted between November 18 and 27, 1996, documented numerous violations in the following areas: organization and personnel, buildings and facilities, equipment, control of components, drug product containers and closures, production and process controls, laboratory controls, and records and reports. Some examples include:

- failure of the quality control unit to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products;
- failure to have separate defined areas or other control systems for manufacturing and processing operations;
- failure to assure that equipment used in the manufacture, processing, packing or holding of a drug product is of appropriate design and of adequate size for its intended use and for its cleaning and maintenance;
- failure to properly store and handle components and drug product containers and closures;
- failure to calibrate instruments, apparatus, gauges and recording devices at suitable intervals; and
- failure to record the performance of each step in the manufacture and distribution of products.

Although similar deficiencies have been identified during past inspections, MBPI has failed to make satisfactory corrections. FDA has determined that continuing problems represent a failure to comply with the regulations that safeguard the drug and pharmaceutical industry. However, the agency is not aware of any injuries to recipients of these products as a result of the noted deviations.

In its letter, FDA requires MBPI to submit a written commitment for achieving full compliance within 10 days. MBPI must also submit a comprehensive plan for correcting all deficiencies within 30 days. The action plan must include corrective actions to ensure that the firm's quality assurance unit functions in an adequate, effective and timely manner, including addressing all quality assurance oversight deficiencies, and to conduct a thorough review of all standard operating procedures to achieve compliance with good manufacturing practices as specified in Subchapter C, Parts 210 and 211, Title 21, *Code of Federal Regulations*.

If MBPI fails to correct these deficiencies, FDA may begin the process for revoking the facility's licenses. Under FDA's procedures, MBPI can request a public hearing before an administrative law judge on the proposed revocation of its licenses. The revocation of the licenses would prohibit MBPI from distributing any of its products in interstate commerce.

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