The Truth About Health

Merck Receives FDA Warning To Fix Manufacturing Deficiencies

Volume 12 Issue 45

Numerous manufacturing deficiencies sited at its West Point, PA, plant are the target of a recent U.S. Food and Drug Administration (FDA) Warning Letter recently delivered to Merck & Company, Inc. The 9-page FDA letter said inspectors found "significant objectionable conditions" in the manufacture of vaccines and drug ingredients. This is the same plant where 1.2 million vaccine doses produced were recalled for sterility reasons in December 2007.

The following is the opening line of the letter: "The Food and Drug Administration (FDA) conducted an inspection of Merck and Company, Inc., West Point, Pennsylvania, between 2007 and January 17, 2008. During the inspection, the FDA investigators documented significant deviations from current good manufacturing practice (CGMP) in the manufacture of licensed biological vaccine products, bulk drug substances and drug components."

Numerous failures and inadequacies were sited in the FDA letter. These were particularly noticeable in the areas of controls on production, quality of product, strength and purity. Here are examples of the numerous items detailed:

* Failure to establish test procedures or other laboratory control mechanisms designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity.
* Failure to assure that equipment used in the manufacture, processing, packing and holding of a drug product is calibrated, inspected, or checked according to a written program designed to assureproperperformance.
* Failed to assure that container closure systems provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of bulk drug substances and sterile solutions used in production.
* Failure to exercise appropriate controls over computer or related systems to assure that changes in master production are instituted and input and output from the computer or related system of formulas are checked for accuracy and maintained.

Production of two vaccines was halted at this facility last year when 1.2 million doses of PedvaxHIB and Comvax were recalled for sterility reasons following discovery in October. The plant also produces ProQuad for measles, mumps, rubella and chickenpox protection; hepatitis A, hepatitis B and meningitis vaccines for children and adults; and Gardasis, used to protect young women against cervical cancer.

As of April 2008 the FDA has given Merck a period of 15 days to respond. If this demand is not met, the FDA can take further enforcement action if the items mentioned in the warning letter are not promptly and adequately corrected.

Source: The U.S. Food and Drug Administration. Warning Letter. April 2008.
http://www.fda.gov/foi/warning_letters/s6756c.htm and http://www.fda.gov/cber/faq/merckqa.htm