



Quality Assurance: Inspection and Product Testing/Screening Program Review

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The inspection and product screening quality assurance program segment developed as part of the SEAM Program was launched on October 25, 2002. The structured program resulted in more inspections of dispensing outlets, inspections at selected ports of entry (POEs), and product screening with the GPHF Minilab to detect products that contained no drug or the wrong drug. The POE screening surveillance was initially focused on selected antimalaria drugs. After one year, the test inventory was expanded to include selected antibiotic drugs, and in March 2005 the inventory was again expanded to include selected antiretroviral drug products.

In addition to the POE program, a parallel postmarketing surveillance program has been initiated for the inspection and Minilab screening of products collected from dispensing outlets. Through the Minilab screening tests of more 1,200 samples obtained primarily from the POEs, three quinine and two erythromycin samples were found to be counterfeit and have no active ingredient. It is of interest to note that no markedly substandard products have been observed in the screening of these legitimate market samples. These observations provide evidence that the upstream compliance activities of registration, record inspection, and physical examination are properly functioning and reflect the improved quality of marketed products when compared to the findings of SEAM baseline studies. The enforcement of this universe of activity—including registration, inspection, physical examination, product screening, and laboratory testing—provides a significant deterrent to marketers of illegal products and thus improves the market for legitimate, conscientious manufacturers and distributors. The accomplishments of and observations on the procedures will be presented.