83810 Medical Devices and Radiological Health

Chapter 48 - Bioresearch Monitoring

Subject SPONSORS, CONTRACT RESE, ORGANIZATIONS AND MONITO	
Product Codes	Data Reporting Product/Assignment Codes
45Z, 46Z 57Z, 99Z	09810 Food Additives 41810 Therapeutics Products 42810 Blood and Blood Products 45810 Vaccines and Allergenic Products

48810 Human Drugs

68810 Veterinary Drugs

#### Field Reporting Requirements

60Z, 61Z

68Z, 69Z

73Z, 74Z

94Z, 95Z

All establishment inspection reports (EIRs), complete with attachments, exhibits, and any post-inspectional correspondence are to be submitted promptly to the assigning Center. If an EIR contains serious findings that raise the possibility of one or more violations of the Federal Food Drug and Cosmetic Act (FFDCA) or other Federal statutes, a copy of the EIR should be forwarded to the District Compliance Branch at the time it is sent to the Center. When an FDA 483 is issued, a copy will be faxed to the Center contact identified in the assignment.

When the District becomes aware of any significant adverse inspectional, analytical, or other information which may affect the agency's new product approval decisions with respect to a firm, the District should immediately notify the responsible Center program office via electronic mail, fax, or by phone.

# **Fda Compliance Program Manual**

**Tao Wei** 

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