

Chapter 48 - Bioresearch Monitoring

Subject SPONSORS, CONTRACT RESEARCH ORGANIZATIONS AND MONITORS	Implementation Date February 21, 2001
	Completion Date Continuing
Data Reporting	
Product Codes	Product/Assignment Codes
45Z, 46Z 57Z, 99Z 60Z, 61Z 68Z, 69Z 73Z, 74Z 94Z, 95Z	09810 Food Additives 41810 Therapeutics Products 42810 Blood and Blood Products 45810 Vaccines and Allergenic Products 48810 Human Drugs 68810 Veterinary Drugs 83810 Medical Devices and Radiological Health

Field Reporting Requirements

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

David Baud



Fda Compliance Program Manual:

FDA Compliance Program Guidance Manual United States. Food and Drug Administration, 1999-02 [FDA Compliance Program Guidance Manual: Foods and cosmetics](#) United States. Food and Drug Administration, 1982 **FDA Compliance Program Guidance Manual, Section IV (Veterinary Medicine)** United States. Food and Drug Administration, 1980

FDA Compliance Program Guidance Manual United States. Food and Drug Administration, 1998-12 **FDA Compliance Program Guidance Manual: Foods and cosmetics** United States. Food and Drug Administration, 1982 **FDA Compliance Program Guidance Manual, Section I (Foods & Cosmetics)** United States. Food and Drug Administration, 1980 **FDA Compliance Program Guidance Manual** United States. Food and Drug Administration, Institutional Review Board Program, 1981 **FDA Compliance Program Guidance Manual** United States. Food and Drug Administration, United States. Department of Health and Human Services, 1988 [FDA Compliance Program Guidance Manual](#) , 2016 [FDA Compliance Program Guidance Manual, Transmittal No. 97-01, October 8, 1996](#) , *FDA Compliance Program Guidance Manual, Transmittal No. 00-09, January 7, 2000* , 2000* **Compliance Program Guidance Manual** United States. Food and Drug Administration. Office of Regulatory Affairs, FDA compliance programs provide guidance and instructions to FDA staff for obtaining information to help fulfill agency plans in the specified program area. These compliance programs neither create or confer any rights for or on any person and do not operate to bind FDA or the public. Alternative approaches may be used as long as said approaches satisfy the requirements of applicable statutes and regulations **FDA Compliance Program Guidance Manual, Transmittal No. 95-39, August 22, 1995** United States. Food and Drug Administration, **FDA Compliance Program Guidance Manual, Transmittal No. 95-43, August 22, 1995** United States. Food and Drug Administration, *FDA Compliance Program Guidance Manual, Transmittal No. 96-09, January 25, 1996* United States. Food and Drug Administration, [FDA Compliance Program Guidance Manual, Section IV](#) United States. Food and Drug Administration, 1993 [FDA Compliance Program Guidance Manual, Section II](#) United States. Food and Drug Administration, 1994 **FDA Compliance Program Guidance Manual** United States. Food and Drug Administration, 1990 **FDA Compliance Program Guidance Manual, Transmittal No. 96-01, January 19, 1996** United States. Food and Drug Administration, *FDA Compliance Program Guidance Manual, Transmittal No. 97-03, October 22, 1996* ,

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