Chapter 48 – Bioresearch Monitoring

Subject	Implementation Date
GOOD LABORATORY PRACTICE (Nonclinical Laboratories)	February 21, 2001
	Completion Date Continuing

Data Reporting	
Product Codes	Product/Assignment Codes
51Z or 52Z 45Z, 46Z 57Z, 99Z 60Z, 61Z 68Z, 69Z 73Z, 74Z 94Z or 95Z	04808 Chemical Contaminants (EPA) 09808 Food Additives 41808 Biologics (Therapeutics) 42808 Biologics (Blood) 45808 Biologics (Vaccines) 48808 Human Drugs 68808 Animal Drugs 83808 Medical and Radiological Devices

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 raising the possibility of one or more violations of the Federal Food Drug & 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. If an FDA-483 is issued, a copy will be faxed to the Center contact identified in the assignment.

If 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.