CHAPTER 48 - BIORESEARCH MONITORING - DRUGS, DEVICES, BIOLOGICS, and FOODS

SUBJECT:	IMPLEMENTATION DATE
INSTITUTIONAL REVIEW BOARD	10/01/94
	COMPLETION DATE
	09/30/97

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
45Z Foods	09809
46Z	
57Z Biologics	*41809 (therapeutics)
	*42809 (blood)
	*45809 (vaccines)
99Z	
60Z Drugs	48809
61Z	
73Z Devices	83809
74Z	

Field Reporting Requirements

All establishment inspection reports (EIR's), complete with attachments, exhibits, and any related correspondence are to be submitted in a timely fashion to the assigning Center.

If an EIR contains serious findings raising the possibility of one or more violations of the FD&C Act 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.

Current Change