Release of Establishment Inspection Reports to the Inspected Establishments Pursuant to Field Management Directive 145
SOPP 8504

Appendix

Letter to accompany EIR to the inspected facility:

Date

Name
Company & Address

Dear [Name]:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility at [Address] on [date] on behalf of the U.S. Food and Drug Administration (FDA). This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to that date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and 21 CFR Part 20. This, however, does not preclude you from requesting, and, possibly, obtaining any additional information under FOIA.

If there are any questions regarding the released EIR information, please do not hesitate to contact me at (301) 827-6191 or write to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Team Biologics Liaison Staff, HFM-605
1401 Rockville Pike
Rockville, MD 20852

Sincerely,

[name]
Team Leader
Team Biologics Liaison Staff
Office of Compliance and Biologics Quality