was obtained, whether protocol-required pregnancy testing was performed prior to administration of study drug to female subjects with child-bearing potential, protocol-required assessments of the extent of periodontal disease, the number of subjects enroled, the formulation of the study drug, the amount of study drug administered to subjects, and the occurrence and reporting of adverse events" (7). Thus, it is evident that all of these reasons correlate with instructions set forth in a typical Clinical Study Protocol.

The Warning Letter concluded with a statement found at the end of all of the FDA's many thousands of Warning Letters:

> Within fifteen (15) working days of your receipt of this letter, you must notify this office in writing of the actions you have taken or will be taking to prevent similar violations in the future. Failure to adequately and promptly explain the violations noted above may result in regulatory action without further notice.

The same issue is revealed by another Warning Letter, where the investigator refused the FDA access to records, and where the FDA issued a Form 483 notice. The investigator (Synergy Health) stubbornly responded to the Form 483 by writing that, "FDA has no jurisdiction to inspect or review Synergy Health's studies" (8). Yet another Warning Letter documents the investigator's refusal to allow the FDA inspectors to see records (9).

IV. ANECDOTAL DESCRIPTION OF AN FDA INSPECTION, FDA'S REQUIREMENTS FOR RECORD KEEPING DURING DRUG MANUFACTURE, AND GUIDANCE FOR RESPONDING TO FDA'S COMPLAINTS

The following letter, which concerns a drug manufacturing facility, provides an anecdotal description of an FDA inspection. The letter provides an anecdotal description that refers to company employees as being "panicked" by the FDA inspection, but what is more important is the letter's account of corrective action that is needed. The anecdotal account in the Warning Letter referred to panic by company employees, and revealed that (10):

> In your response, you refer to an investigation and indicate that two analysts momentarily panicked upon (1) learning that FDA Investigators were approaching the microbiology Lab and (2) seeing used petri plates from the weekend scattered throughout the laboratory … and directed the lab technician to immediately remove the petri plates from the microbiology lab … in an utterly misguided and ill-conceived attempt to clean up the microbiology lab prior to the start of the FDA inspection.

Following the account of this anecdote, FDA's Warning Letter complained about failures in quality control during manufacturing, and poor record keeping. Please note that

[7]Warning Letter No. 07-HFD-45-0601 (June 22, 2007) from Gary Della'Zanna of Division of Scientific Investigations, Office of Compliance, CDER, U.S. Food and Drug Administration.

[8]Warning Letter to Synergy Health Concepts (there is no Warning Letter number) (September 5, 2012) from Steven D. Silverman, Office of Compliance, Center for Devices and Radiological Health, U.S. Food and Drug Administration.

[9]Warning Letter 10-HFD-45-10-02 (October 19, 2009) from Dr Leslie K. Ball, MD, Office of Compliance, CDER, U.S. Food and Drug Administration.

[10]Warning Letter No. WL: 320-15-06 (January 13, 2015) from Thomas Cosgrove, JD, Office of Manufacturing Quality, Office of Compliance, CDER, U.S. Food and Drug Administration.