



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Los Angeles District

19701 Fairchild  
Irvine, California 92612-2506  
Telephone (949) 608-2900

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

February 2, 2007

**W/L 06-07**

Kevin J. Gadawski, President  
First Check Diagnostics, LLC  
13 Spectrum Pointe Dr.  
Lake Forest, CA 92630

Dear Mr. Gadawski:

We are writing to you because between August 30 and September 14, 2006, an inspection of your facility located in Lake Forest, California, conducted by our investigator revealed serious regulatory problems involving your drug-of-abuse kits. Under Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 321(h), these kits are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

Under the Act, manufacturers of medical devices are required to comply with the Quality System Regulation (QSR) for medical devices (Title 21, Code of Federal Regulations (CFR), Part 820). Deviations from these regulations cause medical devices distributed by your firm to be adulterated within the meaning of Section 501(h) of the Act, 21 U.S.C. 351(h). Our inspection found the following device QSR deficiencies:

1. A quality system has not been fully implemented and maintained at all levels of the organization. Specifically you have not established quality policy and objectives, you have not appointed an individual to ensure that quality system requirements are met, your quality plan has not been established and you have not established quality audit procedures. [ 21 CFR 820.20]
2. Document control procedures have not been fully implemented and maintained. Specifically you do not have document control procedures for the origination of procedures or the implementation of document changes. [21 CFR 820.40]

3. Complaint handling procedures have not been established for documenting the receipt, review and evaluation of each complaint. Specifically your firm does not have procedures to fully document each complaint received and subsequent investigation results, if any. [21 CFR 820.198]
4. Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary. Specifically you lack documentation of timely investigation and/or follow-up to at least 21 complaints received during calendar year 2006. [21 CFR 820.198]
5. Appropriate procedures have not been defined for controlling environmental conditions. Specifically your devices are labeled for room temperature or refrigerated storage. Your current manufacturing and warehousing facilities do not have temperature controlling equipment and you have no assurance that devices are maintained below the labeled 86<sup>o</sup> F. [21 CFR 820.70]

We have received your initial undated, as well as your October 4<sup>th</sup>, October 26<sup>th</sup>, November 22<sup>nd</sup>, December 6<sup>th</sup>, and December 8<sup>th</sup> written responses to the FDA-483 issued at the conclusion of the inspection. While you state that you have initiated or completed corrective action for several observations, your responses do not fully address all our concerns. For example:

- You provided a written complaint procedure that does not fully address your complaint situation. Although your procedure provides a form and specifics for action, your response does not include information on periodic review and/or trending; and
- You have also provided a procedure covering product storage and environmental conditions. Again, your procedure does not fully address our concerns. The observation of a temperature indicating device once a day is insufficient to assure that product is in an environment that does not exceed labeled temperature conditions. Additionally, your procedure does not assure the capture of temperatures exceeding the labeled maximum over extended periods of inoperation, such as weekends and holidays.

Furthermore, the Quality System Regulation for medical devices requires not only that procedures are established and written, but that they are also consistently implemented and maintained. We will verify the adequacy of your corrective actions during our next inspection.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of medical devices you are responsible for assuring that your overall operations and the products you manufacture and distribute are in compliance with the law. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in further regulatory action such as seizure, injunction, and/or civil money penalties. Other federal agencies

Letter to Gadawski, First Check Diagnostics, LLC

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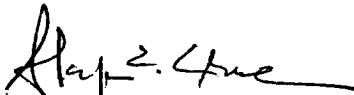
are informed about the Warning Letters issued by FDA so they may consider this information when awarding government contracts for medical device products.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made. If you have any questions or need clarification regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 608-4439.

Your reply should be directed to:

Pamela B. Schweikert  
Director, Compliance Branch  
U.S. Food & Drug Administration  
19701 Fairchild  
Irvine, CA 92612

Sincerely,



Alonda E. Cruse  
District Director