



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

## WARNING LETTER

VIA FEDERAL EXPRESS

AUG 29 2007

Mr. Gwan-Sik Kim  
CEO and President  
All Medicus Co. Ltd  
#7102 Dong-il Techno Town 7<sup>th</sup>  
823 Gwanyang 2-dong  
Anyang, Gyeonggi-do 431-062  
Korea

Dear Mr. Kim:

During an inspection of your firm located in Anyang, Gyeonggi-do, Korea on June 4, 2007 through June 7, 2007, investigator(s) from the United States Food and Drug Administration (FDA) determined that your firm manufactures GlucoDr™ super sensor and GlucoDr™ super sensor Blood Glucose Test Strips. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products 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.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received a response from Mr. Je Young Chang, Senior Research Engineer dated June 18, 2007 concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for validating the device software design to conform to the intended uses, as required by 21 CFR 820.30(g).  
For example,
  - a. The validation results do not meet the pre-determined acceptance criteria, and there was no documentation why the results were acceptable.
  - b. The validation reports do not contain an evaluation of the validation data and activities. Nor does it contain validation analyses and conclusion.

We have reviewed your response and have concluded that it is inadequate because no information is provided other than the fact correction is to be taken by August 10th, 2007.

2. Failure to document acceptance activities, as required by 21 CFR 820.80(e). For example,
  - a. Failure to document the acceptance status of the masks, by the Quality Assurance prior to release for use in production. Instead, they are released by verbal communication.
  - b. The suitability of vial labels released for use in packaging area for various customers is not documented.

We have reviewed your response and have concluded that it is inadequate because no information is provided other than the fact correction is to be taken by August 10th, 2007.

3. Failure to adequately document changes, as required by 21 CFR 820.40(b). For example, different LCD screen suppliers have different dimension specifications. However, the \_\_\_\_\_ for LCD change history failed to include documentation of the change in the incoming acceptance criteria on dimensions for each LCD supplier. It only states the change in the supplier. In addition, a clear set of LCD acceptance specification documentation as supported by design validation is not provided.

We have reviewed your response and have concluded that it is inadequate because no information is provided other than the fact correction is to be taken by August 10th, 2007.

A follow up inspection will be required to assure that corrections are adequate. We will contact the appropriate people and request an establishment re-inspection. An FDA trip planner will be in touch with you to arrange a mutually convenient date for this inspection.

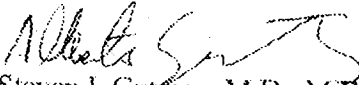
You should take prompt action to correct the violation(s) addressed in this letter. Failure to promptly correct these violation(s) may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)) Also, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to: James Woods (HFZ-440), 2098 Gaither Road, Rockville, MD 20850. If you have any questions about the content of this letter please contact: Tena Wei at 240-276-0393 (telephone) or 240-276-0644 (fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violation(s) noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violation(s) and to bring your products into compliance.

Sincerely yours,

  
for: Steven L. Guman, M.D., M.B.A.  
Director  
Office of in Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health