



OCT 5 2004

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

WARNING LETTER

FEDERAL EXPRESS

Mr. Ade Tarya Hidayat  
President  
Sugih Instrumendo Abadi, Pt.  
Jl. Tembokan Rt. 1/01. Ds. Cipeundeuy  
Padalarang, Jawa Barat, Indonesia 40553

Dear Mr. Hidayat:

During an inspection of your firm located in Jawa Barat, Indonesia on May 31, 2004 through June 3, 2004, our investigator determined that your firm manufactures aneroid sphygmomanometers. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be 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 (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance according to established procedures a process where the results cannot be fully verified by subsequent inspection and test, as required by 21 CFR §820.75(a).

For example, the following processes were not validated: [REDACTED] (a final washing process); compounding/blending of [REDACTED]; compounding/blending of [REDACTED] and [REDACTED]

2. Failure to establish and maintain adequate procedures for acceptance activities. Acceptance activities include inspections, test, or other verification activities, as required by 21 CFR §820.80(a). For example,

- (a) Before products are stored in the warehouse, an additional [REDACTED] test is conducted on [REDACTED] according to a sampling plan. However, the [REDACTED] does not identify the lot/batch/production date of the [REDACTED] tested.

(b) [REDACTED] testing of the [REDACTED] in order to verify that these components meet specifications is conducted by a contract laboratory. The contract laboratory also conducts [REDACTED] testing of the [REDACTED] in order to verify the [REDACTED] the components. The firm has not established procedures for these acceptance activities.

3. Failure to establish and maintain adequate procedures to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR §820.100(a)(1).

For example, the firm's Corrective and Preventive Action Procedure, [REDACTED] lists quality data sources as: [REDACTED]. However, the Quality Assurance Manager reported that although data from quality control activities involving [REDACTED] are collected, they have yet to be analyzed.

4. Failure to establish and maintain adequate procedures to ensure that management with executive responsibility reviews the suitability and effectiveness of the quality system at defined intervals according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR Part 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR §820.20(c). For example:

(a) According to the firm's Management Review Procedure, [REDACTED], the requirements of management reviews are to review and evaluate data from the following sources: [REDACTED]. The agendas for management reviews conducted during [REDACTED] did not include these items.

(b) Procedures for management review are not complete. Specifically, the firm was unable to provide evidence that any supporting documents were reviewed during the meetings; i.e. [REDACTED].

(c) Management reviews were not conducted at defined intervals. Specifically, [REDACTED] does not define the frequency of management reviews. The Quality System Management Representative reported that he conducts management reviews on an ad-hoc basis.

5. Failure to establish and maintain adequate procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements, as required by 21 CFR §820.22.

For example, the firm's Internal Audit Procedure, [REDACTED], does not assure that all applicable parts of the quality system are audited. Specifically, review of the [REDACTED] audit agendas revealed that they did not include corrective and preventive actions, [REDACTED] and process validation.

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

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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. See Section 801(a) of the Act (21 U.S.C. § 381(a)).

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 violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Cardiovascular and Neurological Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Dorothy Lee.

If you need help in understanding the contents of this letter, please contact Dorothy Lee at the above address or at (301) 594-4648 or FAX (301) 594-4672.

Sincerely yours,



Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health