



JUL 7 2004

WARNING LETTER

FEDERAL EXPRESS

Mr. Donald Blacklock
President
Glustitch Incorporated
7188 Progress Way #307
Delta, British Columbia, Canada
V4G 1M6

Dear Mr. Blacklock:

During an inspection of your firm located in British Columbia, Canada from March 15, 2004 through March 18, 2004, our investigator determined that your firm manufactures dental cements, skin protectants, and liquid bandages. 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 establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). For example, no stability studies have been conducted to support the [REDACTED] products.
2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). For example, design controls were not established and implemented for the design of [REDACTED].
3. Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c). For example, no specification has been defined for the [REDACTED].

4. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test, that the process is validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). For example, adequate process validation has not been conducted for the batch manufacturing of [REDACTED]. Additionally, the bond strength test developed in-house has not been validated to show the correlation [REDACTED].
5. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, SOP [REDACTED] Process, does not indicate which personnel can generate a corrective/preventive action request; does not address the use of [REDACTED] used as corrective/preventive action reports; and addresses the use of [REDACTED], which is not utilized as corrective/preventive action reports. In addition, the following deficiencies in the CAPA were noted:

(a) Failure to verify or validate a corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, SOP [REDACTED]. There was no review or signature documented on [REDACTED] for corrective action [REDACTED].

Also, according to SOP 2015, additional effectiveness checks are not required, but may be performed by the president at his discretion. Effectiveness checks are necessary. They provide verification not only that procedures have been properly revised and employees have been adequately trained, but also that a cause determination has been conducted and corrections made.

(b) Failure to document all activities required under Section 820.100, as required by 21 CFR 820.100(b). For example, corrective/preventive action reports do not indicate the individual determining the corrective or preventive action to be taken.

(c) Failure to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, cause was not determined in the investigations of the corrective/preventive action reports [REDACTED].

(d) Failure to identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, in the manufacturers' instructions for use, there is a correct temperature range for the product being investigated. However, the temperatures of the products were not being accurately recorded in storage condition records, and instead the products were listed as [REDACTED]. In corrective/preventive action report [REDACTED].

[REDACTED] No one could explain why the problem in the corrective action report was identified as the temperature range in the instructions for use.

6. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example, the written procedure for conducting batch release tests [REDACTED] is incomplete because it does not include the amount [REDACTED] placed on the [REDACTED], the specific description for positioning of the [REDACTED], and the sample size.

7. Failure to establish and maintain procedures to ensure that device history records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record (DMR), as required by 21 CFR 820.184. For example:

(a) The master batch records for [REDACTED] batches [REDACTED]. However, the batch records revealed that only [REDACTED] was actually added during the processing steps. There was no documentation that an additional [REDACTED] added during the [REDACTED], as you claimed.

(b) The raw data for test results [REDACTED] are not maintained.

8. Failure to include in the DHR the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184(e). For example, labeling used for each lot packaged is not documented in the DHR.

9. Failure to include in the DMRs device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications, as well as production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications, as required by 21 CFR 820.181. For example:

(a) The formulation of [REDACTED], does not contain directions for [REDACTED] of this document, approved with an effective date [REDACTED] contains the incomplete instruction [REDACTED]

(b) DMRs have not been established for [REDACTED]

10. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198. For example, the complaint dated [REDACTED] does not identify the individuals conducting the investigation into the complaint, and does not contain the raw data of test results obtained during the investigation.
11. Failure to have sampling plans written and based on a valid statistical rationale, as required by 21 CFR 820.250(b). For example, there is no statistical rationale for batch release tests (one sample per test).
12. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example, specified requirements were not established to evaluate potential laboratories for the development of a [REDACTED]

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.

Failure to promptly correct these deviations may result in regulatory action without further notice, which may include the refused entry of your affected products until the corrections are completed.

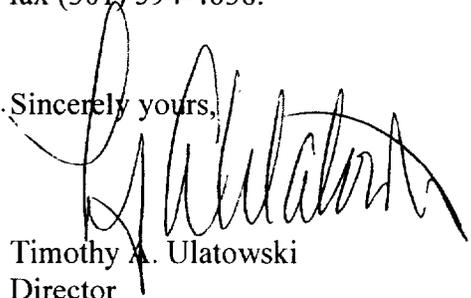
Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these or similar violations from occurring again. Include all documentation of the corrective action you have taken. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. 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 A, Dental, ENT, and Ophthalmic Devices Branch, 2094 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Keisha Thomas.

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If you need help in understanding the contents of this letter, please contact Keisha Thomas at the above address or at (301) 594-4613 or fax (301) 594-4638.

Sincerely yours,



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