



July 29, 2008

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3128

Ref: 2008-DAL-WL-18

**WARNING LETTER****CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. Augusta Clay Kennard, III, President  
NeoChild LLC  
4605 North Stiles Avenue  
Oklahoma City, Oklahoma 73105

Dear Mr. Kennard:

During an inspection of your firm located in Oklahoma City, OK, on April 17, 18, and 22, 2008, and May 1, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the SafeChild System (i.e. the NeoChild™ Enteral Feeding Tubes and Extension Sets), Urinary Drainage Catheters and Collection Kits, PICC Insertion Tray (without catheter), Umbilical Catheterization Tray (without catheter), Lumbar Puncture Needles and Kits, and other types of extension sets with male/female luer locks and clamps. 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 any 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, its 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. We received a response from you dated May 15, 2008, 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 procedures for quality audits and conduct such audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR § 820.22.

Specifically, your firm has not conducted and documented any quality audits of your firm's and contract manufacturers' quality system.

In your response, you provided only the title of SOP 1003 Quality Audit procedure without explaining how quality audits will be conducted and documented at your firm and at your contract manufacturers, how audit deficiencies will be corrected and verified during re-audits, and who will conduct quality audits. Your response is inadequate. Please provide us with a copy of the above-mentioned SOP or a complete description of it, with supplementary information as appropriate to address the noted deficiencies.

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), and failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation, as required by 21 CFR 820.30(b). Specifically, one of your firm's contract manufacturers provided you an undated draft procedure entitled "Design and Development Procedure" and recommended it for your use. Although you, as president of the firm, signed the procedure, you did not date it to indicate whether and when you implemented it. The procedure, moreover, is incomplete in that it does not describe how your firm will perform and document each step of the design development process and ensure that specified design requirements are met.

Your response is inadequate. You provided only the title of SOP 1050 Design Control procedure without explaining the specifics in the procedure or including the full procedure with your response. Please provide us with information demonstrating that you have established the necessary procedures and plans to control device design and development.

3. Failure to establish and maintain adequate procedures for validating the device design to ensure that the device conforms to defined user needs and intended uses, as required by 21 CFR § 820.30(g). Design validation shall include testing of production units under actual or simulated use conditions, risk analysis "where appropriate" (as that term is defined in 21 CFR § 820.1(a)(3)), and documentation of all testing results. Specifically, your firm has not established device design risk analysis procedures, conducted a design risk analysis, or documented the results of the design risk analysis for the silicone and polyurethane enteral feeding tubes and their PVC extension sets or for the pediatric urinary drainage catheters.

Your response is inadequate. In your response, you provided only the title of the SOP 1050 Design Control procedure without explaining the

specifics in the procedure or including the full procedure with your response. You did not explain how will you ensure, in part through testing of production units under actual or simulated use conditions, that your devices conform to defined user needs and intended uses. Please provide us with the necessary information to demonstrate your firm's compliance with design validation requirements. Be advised that the device design validation requirements are your firm's responsibility. While your device design validation may be a joint effort between your firm and your contract manufacturers' firms, your firm is ultimately held accountable for design and production defects in the devices.

In your response, you also stated that you would conduct design risk analysis for the three referenced devices by June 30, 2008. Once you have conducted these risk analyses, please provide us with relevant documentation demonstrating compliance. In addition, you must ensure that you incorporate risk analysis, where appropriate, into all of your design validation activities, as required by 21 CFR § 820.30(g). As stated in 21 CFR § 820.1(a)(3), risk analysis -- which must be performed "where appropriate" -- is considered "appropriate" unless you can document justification otherwise, explaining how, even without risk analysis, the device in question is reasonably expected to meet specified requirements and how you as the manufacturer can carry out all the necessary corrective actions.

4. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's development, as required by 21 CFR § 820.30(e). Specifically, your firm has not maintained design review agenda, design review results, or meeting minutes with the contract manufacturers during your firm's design development of the infant enteral feeding tubes, extension sets, and the pediatric urinary drainage catheters.

Your response is inadequate. You provided only the title of the SOP 1050 Design control procedure without explaining the specifics in the procedure or including the full procedure with your response. Please provide us with details and documentation showing how you will ensure that formal documented design reviews are planned and conducted as required.

5. Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR § 820.30(h). Specifically, your firm has not established design transfer procedures for the infant enteral feeding tubes, extension sets, and the pediatric urinary drainage catheters in order to ensure that you

and your contract manufacturers correctly translate the design into product specifications.

Your response is inadequate. You provided only the title of the SOP 1050 procedure without explaining the specifics in the procedure or including the full procedure with your response. Please provide us with the missing information. Be advised that device transfer is your firm's responsibility. While your device design transfer may be a joint effort between your firm and your contract manufacturers' firms, your firm is ultimately held accountable for design and production defects in the devices.

6. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i). Specifically, your firm's "Design and Development" procedure collected during the inspection and described above did not define what constitutes a design change and how all design changes are to be evaluated, validated or where appropriate verified, documented, and approved. Your firm made changes to the material of your PVC (polyvinyl chloride) enteral feeding tubes (K052903 and K072756), to also market silicone and polyurethane enteral feeding tubes, yet you had no documentation of these design changes and accompanying testing and review. In addition, you changed the indication for use of your IV administration sets (K003854) to instead use PVC extension sets with specific safety connectors, yet you have no documentation of this change and accompanying testing and review.

Your response is inadequate. You provided only the title of the SOP 1050 procedure without explaining the specifics in the procedure or including the full procedure with your response. You did not explain when and how your firm will identify, document, validate or where appropriate verify, review, and approve all design changes, including the ones mentioned above.

7. Failure to establish and maintain a device design history file for each type of device to include or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the design control requirements of 21 CFR § 820, as required by 21 CFR § 820.30(j). Specifically, other than some engineering drawings and device labeling, your firm has not maintained design history files for the silicone and polyurethane enteral feeding tubes, their PVC extension sets, and the pediatric urinary drainage catheters.

Your response is inadequate. You provided only the title of the SOP 1050 procedure. You did not explain the specifics in the procedure or include

the full procedure with your response. Nor did you explain if you will commit to retroactively evaluating and documenting any and all past design activities (including the activities mentioned in this letter) for your marketed devices. Please provide us with the missing information.

8. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR § 820.50. Specifically, your firm has not established the requirements, including quality requirements, that must be met by your suppliers, contractors, and consultants, nor has your firm documented any evaluation of your suppliers, contractors, and consultants based on their ability to meet these requirements. 21 CFR § 820.50(a) and (a)(1). In addition, your firm has failed to define the type and extent of control that you will exercise over these suppliers, contractors, and consultants, for example how you will ensure that the manufacturing processes they perform (extrusion, assembly, packaging, and sterilization) meet all the specified requirements. 21 CFR § 820.50(a)(2).

Your response is inadequate. In your response, you provided the title of SOP 1015 Supplier Evaluation without explaining the specifics in the procedure or including the full procedure with your response. In addition, while you stated that your firm would execute purchasing control agreements with your contract manufacturers by June 30, 2008, you did not specify the content of these agreements nor explain how you will evaluate your contractors' abilities to meet the specified requirements and how you will define the type and extent of your control over their processes. Please provide us with additional information demonstrating how you will comply with the purchasing controls required by 21 CFR § 820.50.

9. Failure to establish and maintain procedures for acceptance activities, including inspections, tests, or other verification activities, as required by 21 CFR § 820.80. Your firm has failed to establish the necessary procedures to ensure that incoming product and finished devices meet acceptance criteria. Specifically, your firm has not established any procedures to define what specific acceptance/rejection criteria you use to inspect, test, accept, or reject the enteral feeding tubes, extension sets, and pediatric urinary drainage catheters prior to releasing them for distribution.

Your response is inadequate. You provided only the titles of SOPs 1021 and 1022 without explaining the specifics of the procedures or attaching the procedures to your response. Please provide us with the missing information.

10. Failure to establish and maintain procedures to ensure that the device history record (DHR) for each batch, lot, or units are maintained to demonstrate that the device is manufactured in accordance with the device master record (DMR) and the requirements of 21 CFR Part 820, as required by 21 CFR § 820.184. Specifically, your firm has not established procedures to ensure that the DHR includes or refers to the location of acceptance records that demonstrate that the device is manufactured in accordance with device specifications, production process specifications, and other criteria and procedures specified in the DMR.

Your response is inadequate. In your response, you provided only the titles of draft SOP 1021 and 1022 procedures without explaining the specifics in the procedures or including the full procedures with your response. While you stated that, under your new supplier's agreements, contract manufacturers will be required to maintain the DHR (including acceptance records), you did not explain if, when, and how your firm will audit these acceptance records to ensure that the manufactured devices meet the required specifications. You are advised that it is ultimately your firm's responsibility to have a complete DHR under 21 CFR § 820.184, which must include or refer to the location of these acceptance records. Please provide us with information demonstrating your firm's compliance with 21 CFR § 820.184.

11. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the other requirements of 21 CFR § 820.198 are met. Specifically, your firm has not established complaint handling procedures for the receipt and handling of complaints.

In your response you stated that this inspectional observation has been "[c]orrected but not verified." This response is incomplete. Please provide us with a copy of the new complaint handling procedure as well as a copy of the training materials for the new procedure and a copy of the training attendance log.

Our inspection also revealed that your firm's devices are misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR § 803 – Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR § 803.17. At the conclusion of the inspection, you stated that your firm has not received any MDR reportable events from the time that you

Page 7 – Mr. Augusta Clay Kennard, III, President  
NeoChild LLC  
July 29, 2008

started distributing devices in March 2007 to present. However, during that time period, you did not have any written procedures for receiving, evaluating, and submitting MDR reports to the FDA.

In your response you provided a copy of your new written MDR procedures for receiving, evaluating, and submitting MDR reports to the FDA. We have reviewed your response and have concluded that it is adequate. The results of your corrective action will be verified at the next scheduled follow-up inspection.

Our inspection also revealed that the SafeChild System, i.e. the NeoChild™ Enteral Feeding Tubes manufactured from silicone and polyurethane and the Extension Sets manufactured from PVC, are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for pre-market approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). These devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring pre-market approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR § 807.81(b). The kind of information you will need to submit in order to obtain approval or clearance for your devices is described on the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, 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, pre-market approval applications for Class III devices to which the Quality System regulation (21 CFR Part 820) 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 violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over


Page 8 – Mr. Augusta Clay Kennard, III, President  
NeoChild LLC  
July 29, 2008

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.

Your response should be sent to Thao Ta, Compliance Officer, Dallas District Office, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204. If you have any questions about the content of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations 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 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 violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

  
Reynaldo R. Rodriguez, Jr.  
Dallas District Director