U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Diasol Inc 8/9/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER

W/L 35-1

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 9, 2010

Monica F. Abelas, President
Diasol, Inc.
1110 Arroyo Street
San Femando, CA 91340

Dear Ms. Abelas:

The Food and Drug Administration (FDA) recently performed inspections at both of your Diasol, Inc. manufacturing sites located at 1110 Arroyo Street, San Fernando, California and 310 S. 43rd Avenue Phoenix, Arizona. The inspections were performed at Diasol Inc. San Femando, CA from May 19 through May 28, 2010 and at Diasol Inc. Phoenix, AZ from January 1 through February 3, 2010. These inspections determined that your firms manufacture liquid and dry hemodialysis concentrates. These products are indicated for use in acute and chronic hemodialysis. 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.

The inspections 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. Similar violations were observed during an inspection of your facility located at 310 S. 43rd Avenue, Phoenix, Arizona from January 1 through February 3, 2010. We received your responses dated February 14 and June 9, 2010 concerning our investigator's observations noted on the Form FDA 483. We address these responses below, in relation to each of the noted violations. Unless otherwise noted, the violations below pertain to the May 28, 2010 San Fernando, CA inspection. These violations include, but are not limited to, the following:

1. Failure to validate to a high degree of assurance and approve according to established procedures a process, where the results of the process cannot be fully verified by subsequent inspection and test as required by 21 CFR 820.75(a). Specifically, the the liquid dialysis concentrate is filled into **(b)(4)** and then delivered to customers **(b)(4).** The validation for the process of cleaning **(b)(4)** has not been completed.

This violation was identified during the February 3, 2010 Phoenix inspection and the May 28, 2010 San Fernando inspection. We reviewed your FDA 483 response letter dated February 14, 2010, and determined it was inadequate because your cleaning validation was incomplete and insufficient data was provided to support your acceptance criteria. Your FDA 483 response letter dated June 9, 2010 to the San Femando, CA inspection indicates you are in the process of performing a larger scale **(b)(4)** validation at both of your manufacturing sites.

Your Validation Protocol **(b)(4)** and data that was provided with your June 9, 2010 response does not take into

account the microbial condition of the **(b)(4)** prior to washing. This protocol states **(b)(4).** This procedure would require validation to insure that **(b)(4)** contaminants will be detected and **(b)(4)** are properly identified.

Your validation procedure describes your acceptance criteria and states **(b)(4)**. However, your validation report does not address **(b)(4).** In addition, your testing described in your Validation Protocol **(b)(4)** does not account for detection of **(b)(4)**. Your validation data and results should ensure that all your acceptance criteria are met.

In addition, your microbiological results provided with your response do not indicate whether the results reflect **(b)(4)**. Your procedure that appears on your **(b)(4)** worksheet indicates **(b)(4).**

2. Failure to establish and maintain acceptance procedures to ensure that specified requirements for in-process products are met as required by 21 CFR 820.80(c). Specifically, your procedure **(b)(4)** states that when processing **(b)(4)** water for production samples that **(b)(4)** will be delivered to **(b)(4)** for incubation and reading. However, it was observed that the delivered volume is not measured and **(b)(4)** are used. In **(b)(4)** and therefore a measured volume is required.

Your response is not adequate. You stated in your June 9, 2010 response that you have updated your procedure t state that **(b)(4)**. You have not indicated how this volume is being measured and a written procedure was not provided. Please provide your water testing procedures for both the Phoenix and San Fernando sites.

3. Failure to document all activities and results required under 21 CFR 820.100 Corrective and Preventative Actio (CAPA). Specifically, your CAPA procedure **(b)(4)** indicates a corrective action log is maintained. However, a CAPA log is not being maintained.

Your response is not adequate. You indicated in your response that the CAPA log has been created and all incidents and actions taken were logged. However, you did not provide evidence of your corrective action.

4. Failure to investigate certain indicators of nonconformities to determine the cause of the nonconformity as required by 21 CFR 820.100(a)(2). Specifically, on 9/15/2009 the pyrogen test on the **(b)(4)** process water was reported by an outside laboratory to have greatly exceeded the limit of **(b)(4)**. There was no documented investigation of this non-conformity until one was prepared during the inspection.

Your response is not adequate. You indicated that the high pyrogen test results for the **(b)(4)** water were a resul of in house contamination. However, you have not provided a detailed investigation determining the root cause o the contamination and have not provided evidence of a corrective and preventative action.

5. The device history record fails to include or refer to the location of the dates of manufacture as required by 21 CFR 820.184(a). Specifically, the device history record for liquid acid concentrate did not record the date when key components **(b)(4)** did not record the date when key components **(b)(4)** were weighed.

Your response is not adequate. Your response states that you have changed your procedure, however a copy of your revised procedure(s) was not provided. In addition, the corrective and preventative action to prevent re-occurrence was not provided with your response.

6. Failure to maintain device history record as required by 21 CFR 820.184. Specifically, the device history record for of Diasol Liquid Bicarbonate shows that this lot was mixed **(b)(4)** and filled into **(b)(4)** on 4/07/2010. However, a sticky note and interviews with plant personnel indicates the lot was mixed and filled on 4/21/2010.

Your response is not adequate. You have indicated that you have made changes to your operating procedure, however a copy of your revised procedure was not provided. In addition, the preventative action to prevent re-occurrence was not provided with your response.

7. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained as required by 21 CFR 820.72(a). Specifically, your calibration program procedure, **(b)(4)** requires a calibration schedule for measuring equipment. However, there is no calibration schedule for measuring equipment.

Your response is not adequate. You have indicated that you have made changes to your calibration procedure, however a copy of your revised procedure was not provided. In addition, the preventative action to prevent re-occurrence was not provided with your response.

8. Failure to document activities with respect to inspection, measuring, and test equipment as required by 21 CFR 820.72(a). Specifically,

a. The **(b)(4)** scale used to weigh the **(b)(4)** for formulation of **(b)(4)** on 5/25/2010 had a calibration sticker which expired on 8/05/2009. There was no documentation that this scale had been calibrated after 8/05/2009.
b.The **(b)(4)** thermometer **(b)(4)** used to record the daily temperature in the counter top incubation ove was put into service on 4/28/2008. The manufacturer recommends that it be calibrated once a year. There is no documentation that this thermometer has been calibrated once a year. There is no documentation that this thermometer has been calibrated since 4/28/2008.

Your response is not adequate. You have indicated that your scale had been calibrated twice in-house since 8/05/2009 and that your thermometer was checked against a NIST traceable thermometer. However, you did not provide evidence of past or current calibration of your **(b)(4)** scale or the **(b)(4)** thermometer **(b)(4)**. Please provide evidence that you have implemented your corrective actions and provide calibration documentation. In addition, the preventative action to

prevent re-occurrence was not provided with your response.

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 being initiated by the Food and Drug Administration 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, 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.

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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.

Your written response should be sent to:

Blake Bevill
Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

If you have any questions about the content of this letter please contact Marco Esteves, Compliance Officer at 949-608-4439.

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. Yo 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,

/s/

Alonza E. Cruse
District Director
Los Angeles District

Cc: Monica F. Abelas, President
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Phoenix, AZ 85009

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