



NEW ENGLAND DISTRICT
MEMORANDUM

Date: December 2, 2008

From: Bradley D. Newsad, CSO
Ramon Martinez, CSO
NWE-DO, Stoneham, MA

FEI: 3005881167
Ameridose, LLC
50 Fountain St
Framingham, MA 01702

To: Chris van Twuyver, SCSO
NWE-DO, Stoneham, MA *MSJG
12/1/08*

Subject: Ameridose Investigation, FACTS #1001276

On November 14, 2008, Investigators Bradley Newsad and Ramon Martinez went to Ameridose, LLC at 50 Fountain St, Framingham, MA 01702 as part of FACTS assignment #1001276. The purpose of the assignment was to collect documents as a follow-up to the 2 prior inspections at Ameridose on 07/21/2008 thru 08/06/2008 and 09/17-18/2008 and to investigate the firms corrective and preventive actions following a recall by the firm on Septmeber 12, 2008. The documents to be collected included: copies of all stock solution logs for all stock soultions made during the months of June, July, and August 2008; copies of the Log of Scripts from the months of June, July, and August 2008; and any documents pertaining to the firms corrective and preventive actions with respect to the firms product recall on 09/12/2008.

Upon arrival at 50 Fountain St, Investigators Newsad and Martinez entered the firm and displayed our credentials and issued an FDA-482 (see Attachment 1) to Ms. Sophia Pasedis, who identified herself as the Vice President of Regulatory Affairs and the most responsible person present at the firm. Investigators Newsad and Martinez requested copies of the stock solution logs for all stock solutions made at Ameridose during the months of June, July, and August of 2008. The stock solution logs were provided by Ms. Pasedis on 11/14/2008 and 11/17/2008. There were 11 different types of stock solutions produced by Ameridose during the months of June, July, and August 2008. Below is a summary of the data from the stock solution logs:

| Exhibit # | Stock Solution | June 2008 | July 2008 | August 2008 | Average/Month |
|-----------|---------------------------|-----------|-----------|-------------|---------------|
| 1 | 0.5% Ropivacaine | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 2 | 1 mg/ml Morphine Sulfate | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 3 | 25 mg/ml Morphine Sulfate | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 4 | 0.2% Ropivacaine | (b) (4) | (b) (4) | (b) (4) | (b) (4) |

| | | | | | |
|----|-------------------------|---------|---------|---------|---------|
| 5 | 10 units/ml Oxytocin | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 6 | 50 µg/ml Fentanyl | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 7 | 0.75% Bupivacaine | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 8 | 0.2 mg/ml Hydromorphone | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 9 | 0.4 mg/ml Hydromorphone | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 10 | 1 mg/ml Hydromorphone | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 11 | 10 mg/ml Hydromorphone | (b) (4) | (b) (4) | (b) (4) | (b) (4) |

Each lot produced of a particular stock solution is documented by an individual stock solution log that includes the drug name, volume produced, and the expiration date. Each stock solution log accounts for the usage of the stock solution in making all other products by the amounts used and the lot numbers of the products produced. In addition to providing Investigators Newsad and Martinez with the stock solution logs, Ms. Pasedis also provided the Logged Formula Worksheets, the Label Reconciliation forms, the QA testing results, and all (b) (4) Status Reports for each stock solution. These additional items have not been included in this report per NWE-DO Compliance Officer Amber Wardwell, but all items have been retained.

Investigators Newsad and Martinez also requested copies of the Log of Scripts for all products sold by Ameridose during the months of June, July, and August of 2008. The Logs of Scripts were provided by Ms. Pasedis on 11/14/2008. The logs include all products sold by Ameridose during the specified time periods. The logs specifically contain the product name and lot number, the date of the prescription, the expiration date of the product, the patient address and phone number, and the cost of the products. The orders vary in size from as small as (b) (4) syringes of Hydromorphone in 0.9% NaCl for (b) (4) (see Exhibit 13, page 4), to as large as (b) (4) syringes of 0.45% Sodium Chloride 2mL in 5mL syringe for (b) (4) (see Exhibit 13, page 7). The logs also provide a summary on the last page of each monthly report that includes the total number of prescriptions and the "total cost" of the products sold. Below is a compilation of those numbers by month:

| Exhibit # | Month | # of Prescriptions | Total Cost |
|-----------|--------|--------------------|------------|
| 13 | June | (b) (4) | (b) (4) |
| 14 | July | (b) (4) | (b) (4) |
| 15 | August | (b) (4) | (b) (4) |

Based on these numbers, the firm averages (b) (4) prescriptions per month for a total cost of (b) (4).

Investigators Newsad and Martinez also requested copies of any corrective and preventive action (CAPA) reports that were generated as a part of the firms recall of all Fentanyl 10 µg/ml 100ml Normal Saline bags with lot #07302008@4 and expiration date 09/13/2008. Ms. Pasedis provided Investigators Newsad and Martinez with a copy of Method Deviation #D08171 report, dated 09/12/2008 (Exhibit 12). Ms. Pasedis stated that Ameridose opened unplanned deviation # D08171 to document actions taken after being notified of a (b) (4) yield test result for a Fentanyl 10µg/mL 100mL Normal Saline bag with lot #07302008@4. The firm reviewed the following lot-related documentation and found: the preparation expiration date was September 13, 2008;

(b) (4) bags were distributed; all customers have re-ordered the product; and no complaints were filed for this lot. The firm could not identify a potential root cause; stock solution testing results used to prepare the affected lot were in specification and no other anomalies were noted for the preparation. The deviation report stated that the firm could not perform another potency testing because they were notified 24 hours before the product was to expire (see Exhibit 12, page 6).


Investigator Martinez asked if any additional actions were taken or any documents were modified as a result of deviation D08171. Ms. Pasedis and Ms. Melanie Cerullo, Director of Quality Assurance for Ameridose indicated no further actions were taken. Ms. Pasedis stated Ameridose is working on implementing a final product testing program that had been recommended to them by FDA officials.

ATTACHMENTS

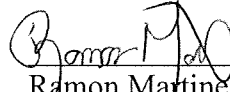
1. FDA-482, Notice of Inspection, issued to Ms. Sophia Pasedis on 11/14/2008.

EXHIBITS

1. Stock Solution Logs of 0.5% Ropivacaine for the months of June, July, and August of 2008; 84 pages.
2. Stock Solution Logs of 1 mg/ml Morphine Sulfate for the months of June, July, and August of 2008; 77 pages.
3. Stock Solution Logs of 25 mg/ml Morphine Sulfate for the months of June, July, and August of 2008; 63 pages.
4. Stock Solution Logs of 0.2% Ropivacaine for the months of June, July, and August of 2008; 30 pages.
5. Stock Solution Logs of 10 units/ml Oxytocin for the months of June, July, and August of 2008; 97 pages.
6. Stock Solution Logs of 50 µg/ml Fentanyl for the months of June, July, and August of 2008; 312 pages.
7. Stock Solution Logs of 0.75% Bupivacaine for the months of June, July, and August of 2008; 192 pages.
8. Stock Solution Logs of 0.2 mg/ml Hydromorphone for the months of June, July, and August of 2008; 113 pages.
9. Stock Solution Logs of 0.4 mg/ml Hydromorphone for the months of June, July, and August of 2008; 45 pages.
10. Stock Solution Logs of 1 mg/ml Hydromorphone for the months of June, July, and August of 2008; 71 pages.
11. Stock Solution Logs of 10 mg/ml Hydromorphone for the months of June, July, and August of 2008; 44 pages.
12. Method Deviation #D08171 report, dated 09/12/2008; 100 pages.
13. Log of Scripts for all products sold by Ameridose for the month of June, 2008; 364 pages.
14. Log of Scripts for all products sold by Ameridose for the month of July, 2008; 387 pages.
15. Log of Scripts for all products sold by Ameridose for the month of August, 2008; 400 pages.



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CC: C. van Twuyver, A. Wardwell