



**NEW ENGLAND DISTRICT
MEMORANDUM**

Date: December 9, 2008

From: Bradley D. Newsad, CSO
Rupa Laverdiere, CSO
HFR-NE250

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

To: Margaret Sands, SCSO
HFR-NE250

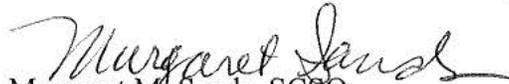
Subject: Ameridose Investigation, FACTS #1004282

On December 8, 2008, we, Investigators Bradley Newsad and Rupa Laverdiere, went to Ameridose, LLC at 50 Fountain St, Framingham, MA 01702 as part of FACTS assignment #1004282. 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 an investigation on 11/14-17/2008. The specific purpose of this investigation was to determine what finished products were made each day from 07/01/2008 thru 07/31/2008 including the product name, dosage/strength, lot #, and lot size.

Upon arrival at 50 Fountain St, we entered the firm and displayed our credentials and issued an FDA-482 (see Attachment 1) to Mr. Gregory A. Conigliaro, who identified himself as the Vice President and General Manager and the most responsible person present at the firm. We requested a listing of all finished products produced from 07/01/2008 thru 07/31/2008 that included the product name, dosage/strength, lot #, and the lot size. Ms. Sophia Pasedis, who identified herself as the Vice President of Regulatory Affairs, Compliance, and Auditing, and Ms. Melanie Cerullo, who identified herself as the Director of Quality Assurance assisted Mr. Conigliaro in retrieving this information. (Memo continued on page 2).

To: CO Bruce Ota, NWE-DO CBr

Records requested were collected at the firm and forwarded to NWE-DO CBr as requested. No further follow up planned by IBr.


Margaret M. Sands, SCSO

Dist:

O: NWE-DO CF⁶(FEI# 3005881167)

CC: M. Sands, B. Ota

The firm provided us with a spreadsheet that includes product name, strength, quantity made, and the lot number for the (b) (4) different lots of finished products produced during the month of July 2008 (see Attachment 2). The lots vary in size from as small as (b) (4) syringes of Morphine Sulfate in 0.9%, 2mg/ml 50ml in 60ml (Lot #07142008@27, see Attachment 2, page 19), to as large as (b) (4) syringes of Lidocaine (PF), 1% 0.2ml in 1ml (Lot #07102008@87, see Attachment 2, page 15).

The data in the spreadsheet is sorted by lot number, which reflects the approximate date of production. Ms. Pasedis stated that the lot numbers, which include a date as a part of the number, reflect the approximate date of production (ex. 07122008@19 reflects July 12, 2008). Ms. Pasedis stated that the actual date of production could be a day, but no more than 2, after the date contained in the lot number. Ms. Pasedis stated that the lot numbers are created when worksheets are started for a given lot, which occurs before the actual production of that lot. Ms. Pasedis stated that worksheets are often started the day before the production of a given lot actually occurs. Ms. Pasedis stated that the exact dates of production are documented, but that verifying these dates would require the batch records for each of the (b) (4) lots that have 07xx2008@x in the lot number. Ms. Pasedis stated that each individual lot is produced on a single day.

Ms. Pasedis stated that the numbers after the @ symbol in the lot number (example – the 19 in 07122008@19) are (b) (4)

(b) (4) Ms. Pasedis stated that the reason that certain lot numbers are skipped or missing from the spreadsheet (see Attachment 1, page 1, there is no 07012008@132) is because (b) (4) (b) (4) or less likely that a lot number was assigned to a lot that was cancelled and never actually produced. Ms. Pasedis stated that occasionally, a customer places an order, the worksheets are started on the production of a lot to accommodate the order, then the order is cancelled, the lot is never produced, and the lot number assigned is unused.

A few abbreviations are used in the product Name and Quantity made columns of the spreadsheet. Listed below are 2 tables stating a description/definition for any of the abbreviations used in these columns that might not be self-explanatory. These description/definitions were stated by Mr. Conigliaro and Ms. Cerullo.

Abbreviation used in product Name column	Description/Definition
D5W	Dextrose 5% in sterile water
D5LR	Dextrose 5% in Lactated Ringers
LR	Lactated Ringers
PF	Preservative Free
SWFI	Sterile water for injection
NS	Normal Saline
ADD-EASE	A proprietary device that includes a IV bag and vial
MEDNET	Glass syringe with a specific software barcode
NONMEDNET	Glass syringe with any other type of special barcode

Abbreviation used in product Quantity made column	Description/Definition
SYR/SYRING	Syringe
BAG/BAGS	IV Bag
EA	Each – this abbr. is used only for 50ml IV Bags
CASS	Cassette – these are used in proprietary drug delivery systems
IPUMP	I-Pump – this is a proprietary bedside drug delivery system

We requested a second copy of the data in Attachment 1 with the data sorted by product name, which was provided by Ms. Cerullo (see Attachment 3).

ATTACHMENTS

1. FDA-482, Notice of Inspection, issued to Mr. Gregory A. Conigliaro on 12/08/2008.
2. A listing of all finished products produced from 07/01/2008 thru 07/31/2008 sorted by lot number, including the product name, dosage/strength, lot number, and the lot size; 50 pages.
3. A listing of all finished products produced from 07/01/2008 thru 07/31/2008 sorted by product name, including the product name, dosage/strength, lot #, and the lot size; 50 pages.




Bradley Newsad, CSO and Rupa Laverdiere, CSO