Establishment Inspection Report	FEI:	**3005881167**
Ameridose LLC	EI Start:	07/8/2010
Framingham, MA 01702-6211	EI End:	07/8/2010

SUMMARY

(Written by Inv. Emerson)

An inspection of this facility was conducted at the request of CDER Office of Compliance, Division of New Drug Labeling and Compliance, to specifically investigate the manufacture and distribution of Nicardipine IV bags (Attachment 2). The inspection was conducted as a Pharmacy Compounding Assignment, PAC 56D015 and FACTS ID 1168481.

In 2008 there were two FDA inspectionin 2008. The first inspection occurred 7/21 thru 8/6/08, at the conclusion of the inspection a six item 483 was issued to management for the following: 1) testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release; 2) written procedures are lacking which describe in sufficient detail the identification, sampling, testing, approval, and rejection of components; 3) master production and control records are deficient in that they do not include a statement of theoretical yield and minimum, maximum, and yield percentages; 4) batch production and control records do not include results of the inspection of the packaging and labeling area before and after use for each batch of drug product produced; 5) batch production and control records are deficient in that they do not include a statement of the actual yield and percentage of theoretical yield; and 6) written production and process control procedures are not followed in the execution of production and process control functions. The inspection classification is pending. On 9/17/08 thru 9/18/08 a second FDA inspection was performed to follow up on additional items from the 7/21-8/6/08 inspection. At the conclusion of this inspection, there was no FDA 483 List of Observations issued.

This inspection did not include review of corrective actions to the previous FDA 483. This was a directed inspection specifically to cover the admixing and distribution of Nicardipine IV. This inspection determined that this facility continues to repack liquid prescription and OTC drug products, they admix epidural solutions for use in facilities, and they admix any other drug product as requested by their customer. They do not apply patient names to these individual products. The only product that they make from a prescription with a specific patient name is dialysis solutions which are used for acute renal failure within an ICU.

The firm currently admixes Nicardipine IV bags in four different dosages for use by any of their customers. There are (b)(4) different customers currently purchasing the IV Nicardipine bags. The individual customers acquire the Nicardipine vials and send them to Ameridose for admixing. Ameridose does not purchase the Nicardipine injectable vials themselves. They are providing a controlled mixing service for their customers per Mr. Conigliaro. At the time of the inspection, the firm was not operating their clean rooms and there was no mixing of Nicardipine at the site. The inspection was then closed and moved to their second location in Westborough, Massachusetts. There was no FDA 483 issued and no samples were collected.

A copy of this report should be mailed to Mr. Gregory Conigliaro, Vice President and General Manager, at the mailing address listed below.

ADMINISTRATIVE DATA

(Written by Inv. Degarmo and Inv. Emerson)

Inspected firm:	Ameridose LLC
Location:	50 Fountain St Framingham, MA 01702-6211
Phone:	508-820-0606
FAX:	508-475-0421
Mailing address:	50 Fountain St Framingham, MA 01702-6211
Dates of inspection:	7/8/2010
Days in the facility:	1
Participants:	Debra M. Emerson, Investigator Stacey S. Degarmo, Investigator

On 7/8/10, Investigator Emerson and Investigator Degarmo displayed their credentials to Ms. Geri Weinstein, Director of Human Resources. Investigator Emerson and Investigator Degarmo also displayed their credentials to Ms. Sophia Pasedis, Vice President of Regulatory Affairs and Compliance, and a FDA-482, Notice of Inspection was then issued to Sophia Pasedis, Vice President of Regulatory Affairs and Compliance. Ms. Pasedis was identified as the most responsible person available at the initiation of the inspection.

Also in attendance were Mr. Samuel Penta, Ms. Cheryl Lathum, and Mr. Leo McKenna from the Massachusetts Board of Registration in Pharmacy.

HISTORY

(Written by Inv. Emerson)

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INTERSTATE COMMERCE

(Written by Inv. Emerson)

The firm currently manufactures and repackages drug product for customers inside and outside of Massachusetts. The firm ships product locally to customers via couriers and also (b) (4) The firm ships to customers outside Massachusetts (b) (4)

JURISDICTION

(Written by Inv. Emerson)

The firm currently repacks and manufactures prescription drug products which are FDA regulated drug products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(Written by Inv. Degarmo and Inv. Emerson)

Gregory Conigliaro, Vice President and General Manager. Mr. Conigliaro has been with the firm and in his current role since it opened in July 2006. He is one of four owners of the company. He stated that he is responsible for the overall day to day management of the firm and works closely with Ms. Pasedis on regulatory affairs and compliance matters. Mr. Conigliaro is the registrant listed for the facility with the DEA.

Sophia Pasedis, Vice President Regulatory Affairs and Compliance. Ms. Pasedis reports to Mr. Greg Conigliaro. Ms. Pasedis has been with the firm since its inception about 5 years ago. She has been in her current role for approximately 3 years. She stated that her responsibilities include the overall compliance of both facilities; oversight of the standard operating procedures; and acts as Pharmacist in Charge/Manager of Record for the Framingham facility.

The firm provided a copy of the Establishment Registration from 2009 (Exhibit 1 p. 2-3) and they also provided a copy of the 2010 electronic Establishment Registration (Exhibit 1 p. 1). Mr.

Conigliaro stated that with the change to the electronic submission of the FDA Establishment Registration, the system only allows the establishment to pick one business type. Mr. Conigliaro stated that when they registered each site, they registered each facility as a "repacker".

MANUFACTURING/OPERATIONS

(Written by Inv. Emerson)

The Framingham facility is currently under renovation and is only repacking oral solutions. As part of the renovation, the firm replaced all HEPA filters. All IV mixing has been transferred to the Westborough facility during this shutdown. The plan is for the IV mixing rooms to be operational within (b) (4). There are (b) (4) hoods in the Framingham facility and the admixture room is approximately (b) (4)

On 7/8/10, during a walk thru of the facility with Ms. Pasedis and Mr. Conigliaro, the clean rooms were all empty as they are in shutdown. We walked thru receiving and shipping then thru the warehouse. There was limited storage of drug products in the warehouse as this facility is not currently in operation for their IV drug products. There were approximately (b) (4) staff in the repacking room. They were engaged in repackaging oral Acetaminophen and Metoclopramide.

Nicardipine IV bags

Ms. Pasedis stated that they started making the IV Nicardipine bags in 2006 at the request of one of their customers located in (b) (4). Ms. Pasedis stated that they used commercial Nicardipine vials which were provided to them by their individual customers. Ms. Pasedis stated that they have supplied the IV Nicardipine bags to (b) (4) different customers. Ms. Pasedis stated that the firm stopped making these Nicardipine IV bags last Friday after they received a letter from EKR Therapeutics notifying them that there was an IV Cardene on the market. Ms. Pasedis stated that she "had no idea Cardene IV was on the market". Mr. Conigliaro came into the room later and stated that Ameridose received a letter from EKR Therapeutics on 6/30/10 and Mr. Conigliaro stated that he believes it is a competitive issue with EKR Therapeutics. Mr. Conigliaro stated that they will continue to produce Nicardipine IV bags. Ms. Pasedis then again stated that they are not going to make the Nicardipine IV bags. Mr. Conigliaro then stated that "this is ridiculous" and that the Nicardipine vials are given to Ameridose by the "hospital and they admix it for them".

As the clean rooms were not in operation due to shutdown, Ms. Pasedis stated that all mixing of IV products including Nicardipine had been transferred to their Westborough facility. Ms. Pasedis stated that prior to the shutdown, either site could make these IV Nicardipine bags.

NDC Numbers

(Written by Inv. Emerson)

Ms. Pasedis explained that the firm will apply an NDC number to any product that they manufacture at the request of their individual customer. The firm has approximately 1800 different NDC

numbers. Ms. Pasedis explained their NDC numbering, the first five numbers are the firms labeling code, the next four numbers are the product code, and the last 2 numbers are the size. Ms. Pasedis explained that the firm does not list any of these NDC numbers with FDA. Ms. Pasedis explained that the firm issues these NDC numbers thru an internal Ameridose committee. These NDC numbers are used at both the Framingham and Westborough facilities.

The NDC numbers used for Nicardipine IV bags are the following:

Nicardipine 25mg/250ml, on 7/26/07 Ameridose issued the following NDC: 24200-0110-10
Nicardipine 20mg/200ml, on 2/26/10 Ameridose issued the following NDC: 24200-0111-11
Nicardipine 50mg/250ml, on 6/2/10 Ameridose issued the following NDC: 24200-0112-10
Nicardipine 40mg/200ml, on 6/3/10 Ameridose issued the following NDC: 24200-0113-11

During our facility tour on 7/8/10, staff were repackaging oral Metoclopramide and oral Acetaminophen. The NDC number that was applied to the Acetaminophen product was 99999-0015-30. Ms. Pasedis was asked about this NDC number that Ameridose applied to the Acetaminophen product as the labeler code is not the same as is used on the Nicardipine. Ms. Pasedis states sometimes their customers request that a different NDC number be put on the repackaged or manufactured products and that they will label these products as requested by their customers. A labeler code of 99999 is not associated with any registered drug labeler within the FDA labeler code website.

LOT NUMBERS

(Written by Inv. Degarmo)

The firm has defined their own lot numbering system based on the date manufactured and a sequential numbering system. For example, lot number AABBCCCC@X, is determined by the following:

(b) (4)

[redacted]

REFUSALS

(Written by Inv. Emerson)

There were no refusals encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

(Written by Inv. Emerson)

As this facility was not manufacturing the Nicardipine bags, we left this facility and went with Mr. McKenna, Mr. Penta, and Ms. Latham to the Westborough, Massachusetts facility.

ADDITIONAL INFORMATION

(Written by Inv. Emerson)

In December 2008 the firm opened a second facility located at 205 Flanders Road in Westborough, Massachusetts.

SAMPLES COLLECTED

(Written by Inv. Emerson)

There were no samples collected during this inspection.

ATTACHMENTS

1. FDA 482, Notice of Inspection, dated 7/8/10
2. E-mail and Letter (13 pages)

EXHIBITS COLLECTED

1. Establishment Registrations (3 pages)

Debra M. Emerson, Investigator

Stacey S. Degarmo, Investigator