DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 214-253-5200	3/13-17/06
	FEI NUMBER 3005623291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jane Patel, Pharmacy Manager

FIRM NAME	STREET ADDRESS
D.R. Pharmacy, Inc.	501 Andrews Highway Suite #100
CITY, STATE AND ZIP CODE Midland, TX 79701	TYPE OF ESTABLISHMENT INSPECTED Pharmacy Compounder

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

In regard to compounded drug preparations:

Observation #1

For standard operating procedures, the firm relies on a guidance document from (b) (4) (b) (4) which is in a binder entitled, "Compound Standard Operating Procedures". The document was identified by the firm's manager as the current standard operating procedure for all compounding operations.

Review of the "Compounding Log" for the period between 2002 and the present for approximately (b) (4) different preparations revealed that the SOP has not been followed in that:

A. Air temperature and humidity in the compounding area is not monitored and documented as required per section II.001.

B. The final compounded product is not visually checked for particulate matter as required per section VI.001.

C. Media fills are not conducted as required per section VI.002.

Some examples of compounded drug products prepared since 2002 include the following:

- Budesonide 0.5mg/2ml NS (b) (4) (b) (4) lot #060803COBO ("MDATE": 3/8/06)
- Albuterol 1.25mg/Cromolyn Sodium 20mg/Ipratropium Bromide .1mg (b) (4) (b) (4) lot #051215COAIP ("MDATE": 12/15/05)
- Dexamethasone 0.2mg/3ml NS, lot #051205 ("MFG. DATE:" 12-15-05)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Stephen D. Brown	Stephen D. Brown, Investigator	3/17/06

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 214-253-5200	3/13-17/06
	FEI NUMBER 3005623291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Jane Patel, Pharmacy Manager	
FIRM NAME D.R. Pharmacy, Inc.	STREET ADDRESS 501 Andrews Highway Suite #100
CITY, STATE AND ZIP CODE Midland, TX 79701	TYPE OF ESTABLISHMENT INSPECTED Pharmacy Compounder

Observation #2

After 2/03, the firm did not conduct testing for potency of any compounded drug products. For example,

- Budesonide 0.5 mg/2ml (b) (4) (b) (4), lot #060803 ("MDATE:" 3/8/06)
- Budesonide 0.25mg/2ml (b) (4) (b) (4), lot #063101 ("MDATE:" 1/31/06)
- Albuterol 1.25mg/3ml, lot #063101 ("MGF DATE:"1/31/06)

Observation #3

In regard to environmental monitoring in the Laminar Flow Hoods (Class 100 area) installed in 2002 (Used prior to 1/06) and 2006:

a. There is no documentation to indicate that the current Laminar Flow Hood (Installation date: 1/06) used to compound drug products has been certified to Class 100 conditions.

b. Monitoring for viable/non-viable air particulates has never been performed in either hood.

c. Monitoring of personnel and surfaces in either hood for bioburden has never been performed.

d. The (b) (4) used to disinfect the surfaces inside either LAF hood has never been filtered with a 0.22 micron filter prior to use.

Observation #4

The (b) (4) (b) (4), which is used for the (b) (4) (b) (4), is mounted inside the Laminar Flow Hood at an angle which places the device outside the laminar flow hood. As a result, the laminarity of the airflow inside the hood could be compromised during compounding operations. Management indicated that the (b) (4) was routinely used in the position indicated during compounding operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Steph D. Brown	Stephen D. Brown, Investigator	3/17/06

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 214-253-5200	3/13-17/06
	FEI NUMBER 3005623291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jane Patel, Pharmacy Manager

FIRM NAME	STREET ADDRESS
D.R. Pharmacy, Inc.	501 Andrews Highway Suite #100
CITY, STATE AND ZIP CODE Midland, TX 79701	TYPE OF ESTABLISHMENT INSPECTED Pharmacy Compounder

Observation #5

(b) (4) is routinely used as a preservative in various compounded drug products. To date, the firm has not conducted preservative effectiveness testing of (b) (4) Some examples of products and specific lots which contain (b) (4) include the following:

- Budesonide 0.5mg/2ml NS ((b) (4) (b) (4) lot #060803 ("MDATE:" 3/8/06, Expiration date unspecified)
- Dexamethasone 0.2mg/3ml NS SOL., lot #051205 ("MFG. DATE:" 12-15-05, "EXP. DATE:" 02-14-06)
- Albuterol 2.5mg and Ipratropium Bromide, lot #050511COAI ("M.DATE:" 12/05/05, "E. DATE:" 02/05/05)

Observation #6

The firm re-uses non-sterile gowning and hairnets during compounding operations. On 3/14/06, two used (b) (4) gowns and one paper hairnet were observed on a shelf in the firm's drug storage area. Management indicated that the two gowns and one hairnet had been used multiple times for compounding operations.

Observation #7

The plastic pouches (b) (4)) used to package the final compounded, (b) (4) On 3/14/06, one bag of (b) (4) currently in use was observed to be open and unsealed in the firm's drug container storage area which also operates as an employee lunchroom.

Observation #8

In regard to the (b) (4) (b) (4) of compounded drug products:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Stephen D. Brown, Investigator	3/17/06

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 214-253-5200	3/13-17/06
	FEI NUMBER 3005623291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jane Patel, Pharmacy Manager

FIRM NAME	STREET ADDRESS
D.R. Pharmacy, Inc.	501 Andrews Highway Suite #100
CITY, STATE AND ZIP CODE Midland, TX 79701	TYPE OF ESTABLISHMENT INSPECTED Pharmacy Compounder

a. There is no data to demonstrate (b) (4) for the (b) (4) (b) (4)

b. The (b) (4) (b) (4) are not (b) (4) of the compounded drug products.

c. The firm routinely re-uses (b) (4) (b) (4) about (b) (4) times before using a (b) (4) There is no data to support the re-use of (b) (4) (b) (4) The firm has no record to document when the (b) (4) of different lots.

d. The firm has no data to indicate if active ingredient(s) from different formulations of compounded drug products are (b) (4) (b) (4) (b) (4) between (b) (4)

Observation #9

The firm uses sterile (b) (4) Management confirmed that the (b) (4) . Between uses, the (b) (4) is sanitized with (b) (4) Management indicated that the (b) (4) is sanitized between lots (b) (4) (b) (4) (b) (4) .

To date, the firm has not generated any data to substantiate the sanitization of the (b) (4) with (b) (4) There is no assurance that potential residue on the (b) (4) consisting of different active ingredients is effectively removed.

Observation #10

There is no data to demonstrate that the compounding and filling process for the firm's compounded drug products has been validated. Specifically,

a. There is no data to indicate that the mixing steps (b) (4) for various compounded, drug products will provide effective homogenization of compounded ingredients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Stephen D. Brown	Stephen D. Brown, Investigator	3/17/06

b. There is no data to show that the (b) (4) (b) (4) (b) (4) will consistently deliver required volumes. There is no documentation of (b) (4) QC checks in order to ensure that fill volumes are correct.

c. There is no data to show that the (b) (4) (b) (4) will consistently seal individual (b) (4) to required specifications. On 3/13/06, a plastic tote containing approximately (b) (4) rejected (b) (4) was observed in the filling area adjacent to the (b) (4) Management indicated that all of the (b) (4) had been rejected due to problems with leaking after sealing.

Observation #11

The firm maintains compounded drug products under different conditions including (b) (4) (b) (4). In addition, all compounded drug products are allowed to be stored (b) (4) (b) (4)

There is no data to support the following expiration dates for compounded inhalation drug products:

- (b) (4) day expiration for (b) (4)
- (b) (4) day expiration for product (b) (4)

In addition, the firm has not generated stability data to support expiration dates.

Observation #12

The firm routinely stores compounded drug products in a (b) (4) pending delivery to patients. The firm has no data to demonstrate that the potency of the active ingredient in various compounded preparations is not adversely affected by the (b) (4). The inspection revealed that the firm was storing at least (b) (4) lots of compounded drug products in the (b) (4). Some of these consist of the following:

- Albuterol Sulfate 2.5mg/Ipratropium Bromide 0.5mg/Budesonide 0.25mg/3.5 ml Normal Saline (Lot #032505) (This lot was prepared on 5/25/03)

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 214-253-5200	3/13-17/06
	FEI NUMBER 3005623291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jane Patel, Pharmacy Manager

FIRM NAME	STREET ADDRESS
D.R. Pharmacy, Inc.	501 Andrews Highway Suite #100
CITY, STATE AND ZIP CODE Midland, TX 79701	TYPE OF ESTABLISHMENT INSPECTED Pharmacy Compounder

- Tobramycin 150mg/5 ml Normal Saline (Lot #062601COTO)
- Albuterol Sulfate 2.5mg/Chromolyn Sodium 20mg/(b) (4) (b) (4) (Lot #062302)

Observation #13

Review of the firm's 'Compounding Log' for the period between 3/05 to the present revealed that 42 of (b) (4) lots did not include expiration dates. For example,

- Budesonide 0.5mg/2ml, lot #060803 ("MDATE:" 3/8/06, no expiration date)
- Budesonide 0.5 mg/2ml, lot #063101 ("MDATE:" 1-31-06, no expiration date)
- Albuterol 1.25mg and Ipratropium Bromide 0.5mg/3.5 ml NS, lot #063101COAI ("MDATE:" 1-31-06, no expiration date)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Steph D. Brown	Stephen D. Brown, Investigator	3/17/06