

DEPARTMENT OF HEALTH AND HUMAN SERVICES BCR-EF cling Pharma

Food and Drug Administration 555 Winderly Place, Suite 200 Maitland, FL 32751 Telephone: (407) 475-4700 FAX: (407) 475-4768

Date:

To:

August 16, 2011

Responsible Firm

Walgreens Co., dba Chroniscript

1250 NW 7th St. Suite 205

Miami, FL 33125

Edwin J. Gorney, SCSO

FEI: 3006723358

From:

Kelly M. McNeill, Craig A. Garmendia

Investigators, Florida District

Subject:

Investigation into the contamination of Avastin and the subsequent outbreak of

Streptococcus mitis/ oralis in patients with wet age-related macular degeneration (AMD).

FACTS assignment # 1305865 requested a visit to Walgreens for information regarding recalled lots of Avastin in which 12 cases of *Streptococcus mitis/ oralis* were reported to have infected patients' eyes. The assignment also instructed to collect samples of product still available from affected lots.

Avastin (bevacizumab) for Intravenous Use is an anti-angiogenesis neoplastic prescription drug approved for the treatment of metastatic colorectal cancer, non-small cell lung cancer, glioblastoma, and metastatic kidney cancer; but Avastin has an off-label use for the treatment of wet age-related macular degeneration (AMD). Through this application, Avastin functions in binding to and inactivating the growth of blood vessels in the macula that can lead to the leakage of blood and fluids into the macula. The product comes from the manufacturer in a one-time-use vial as a clear liquid that is to be partitioned into individual one-time-use syringes.

TO:

This memo summarizes the investigation into Avastin contamination that was distributed by Walgreens, dba Chroniscript, and the subsequent outbreak of *Streptococcus mitis/ oralis* in patients with AMD. Investigators obtained information from the distributor and doctors that treated the patient's with the infection, along with culture reports from (b) (c)

Edwin J. Gorney, Supervisory Investigator

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HFR-SE250/HFR-SE240 (MBT)/HFR-SE230

cc:

HFR-SE2595 (Recall-WAL)

cc:

HFR-SE2590 (MSD)

cc:

HFR-SE2585 (DAD)

On 07/20/11, Investigator McNeill and I arrived at Walgreens and spoke with an Eduardo (nmi) Ruiz, General Manager of Walgreens Store # 15106. The Florida Department of Health (DOH) arrived at Walgreens shortly thereafter. We spoke with an Ann Schmitz, Regional Epidemiologist, and Luis Nieves, Operations Management Consultant Manager, and indicated that we were there about the Avastin issue. DOH notified us that they were there for a routine inspection of the facility.

Through discussions with Mr. Ruiz, it was determined that Walgreens bought Chroniscript in May 2011 and is now dba Chroniscript. Mr. Ruiz described the operations of his Walgreens facility as it pertains to Avastin. Doctors at various eye centers in South Florida write a prescription for Avastin, the prescription is sent to Walgreens who in return orders the pharmaceutical which is obtained from (b) (4)

(b) (4)

Please see Attachment # 1 for copies of the Avastin invoice from Walgreens to Infupharma LLC. where the product is partitioned into separate one-time-use syringes for each prescription and returned to Walgreens. Please see Attachment # 2 for copies of Walgreens pick-up/ delivery slips. Finally, the product is delivered to each individual doctor's office for use, after Walgreens has labeled each syringe package with the patient's information on it. Please see Attachment # 3 for a copy of the legal agreement between Walgreens and Infupharma.

Mr. Ruiz indicated that the firm became aware of infections with regards to the Avastin on July 10, 2011, and that by July 11, 2011 all doctors had been notified of the potential issue via phone call. In addition Walgreens released a primary recall notice identifying the indicated lots, 06222011 thru 07072011 and instructing that the lots be quarantined. Walgreens released a second noticed on July 15, 2011 broadening the recall to include every lot of Avastin. The recall instructed consignees to discontinue the use and distribution of Avastin. The instructions went on to request quarantining the product and contacting Chroniscript for further instructions. In addition, the clinics were to count and record the number of syringes they possessed. Please see Attachment # 4 for a copy of the two recall notices released. Please see Attachment # 5 for a copy of a report of Avastin lots prepared. Please see Attachment # 6 for a copy of a report of patients who received Avastin from May 4, 2011 thru July 7, 2011. Please see Attachment # 7 for an Avastin MD distribution list.

In regards to the infections, Mr. Ruiz indicated that the firm was aware of 12 infections that had occurred. Mr. Ruiz was aware of nine infections a(b) (4) two infections at the (b) (4) , and one infection at the (b) (4) To Mr. Ruiz's knowledge(b) (4) (b) (4) which handled the medication for some of the doctors, had six unused syringes and (b) (4) s had four syringes. Mr. Ruiz had no knowledge of syringes at the (b) (a) . The syringes not at Walgreens were sampled by DOH. An overview of the lots in quarantine at Walgreens found no unused syringes for the lots associated with the initial recall. However, numerous syringes were identified as being of interest to HQ, and thus were sampled on July 21, 2011; these included: Sample # 704999 (14 - 1 cc unused syringes - lot # 07072011 and 1 unopened [not used to fill syringes but reported to be same parent Genentech lot] 16 mL vial of Avastin - lot # 8834496), Sample # 705000 (1 - 1 cc used syringe - lot # 06222011), and Sample # 705001 (2 -1 mL unused syringes – lot # 07112011 and 1 – opened [reported to be used in the filling of syringes] 16 mL vial of Avastin – lot #8834496).

A documentary sample was collected (DOC 679739) in which Mr. Ruiz signed an affidavit on July 21, 2011 stating the documents dealing with shipments of Avastin in which Walgreens received the pharmaceutical from (b) (4), delivered the pharmaceutical to Infupharma, received the filled syringes from Infupharma, and delivery of the syringes to customers. The affidavit also stated the information

about the recall. Please see Attachment #8 for a copy of the signed affidavit with sample number DOC 679739.

On July 25, 2011 Investigator McNeill and I visited (b) (4) s. (b) (6), (b) (4) , Administrator and COO, informed us that 45 patients were injected with the affected lot, but only two patients were infected. Please see Attachment # 9 for a list of patients injected with Avastin since June 23, 2011. He notified us that Holly Montejano from DOH had been in contact with him. (b) (6), (b) (4) indicated that only (b) (6), (b) (4) performed the injections of Avastin. We were able to talk with (b) (6), (b) (4) via telephone call. (b) (6), (b) (4) was able to describe the procedure for the Avastin injections. Please see Attachment # 10 for the procedure. The following day the patients were seen, two patients showed signs of an infection, taps were taken, and were subsequently prescribed vancomycin and amikcain. Three days later taps showed patients were positive and were subsequently prescribed vancomycin and terramycin. The following day the patients received a vitrectomy. (b) (6), (b) (4) indicated that the patients are progressing well but that at least minor eye damage will be permanent. (b) (6), (b) (4) provided the documentation from the patients' charts from the date of the procedure that caused the infection to July 25, 2011.

On July 25, 2011 Investigator McNeill and I visited (b) (4) **(b) (4)** We spoke , Ophthalmology Technician, in the waiting room of the facility. to a (b) (6), (b) (4) Investigator McNeill asked if we could go somewhere quieter in order to discuss why we were there. (b) (6), (b) (4) stated no and instructed us to contact (b) (6), (b) (4) and schedule a meeting with her. She went on to say that they were instructed by DOH and the Center for Disease Control and Prevention (CDC) not to give documents to the FDA without the meeting. I asked (b) (6), (b) (4) who , (b) (6), (b) (4), and a told them this and she responded with the names (b) (6), (b) (4) fourth person for which she had no name. I then clarified with (b) (6), (b) (4) tha ((b) (4) would not be willing to give us the documents we requested, she confirmed this statement, and we left the firm. After talking (b) (6), (b) (4) in a conference call between FDA, CDC, and DOH on July 27, 2011, (b) (6), (b) (4) was offered an invitation to join FDA in attempting to retrieve records from (b) (4) (b) (6), (b) (4) declined the invitation.

On July 28, 2011 I called **(b) (4)** at 10:22am and spoke with a **(b) (6), (b) (4)** . Office Manager. After describing the documents we were attempting to collect, (b) (6), (b) (4) indicated she needed to deliver the message to (b) (6), (b) (4) and she would have to return our call in roughly an hour after (b) (6), (b) (4) was out of a meeting. After not receiving a call, I called (b) (4) at 1:18pm at which indicated that (b) (6), (b) (4) from the CDC told (b) (6), (b) (4) to have the FDA point (b) (6), (b) (4) that (b) (6), (b) (4) is from DOH, which is a state agency, and contact him. I explained to (b) (6), (b) (4) not CDC, which is a federal agency. I went on to explain that we had talked with (b) (6), (b) (4) the previous day and that the FDA, a federal agency, has no direct connection to the state agency. I further stated the laws and regulations that give FDA the authority to request and receive the patients' records as it relates to the outbreak that was linked to an FDA regulated product. (b) (6), (b) (4) indicated she would relay the message to (b) (6), (b) (4) and we would be contacted within the half hour. I contacted (b) (4) at 2:43pm and was told by the receptionist that (b) (6), (b) (4) and (b) (6), (b) (4) were not available. I stressed the importance of the matter and that the failure to contact me in a half hour would result in my supervisors being notified and the issue would have to be resolved through them.

On August 3, 2011 I was instructed by management to return to **(b)** (4) to obtain the medical records. I was also instructed to take a box of office paper to the firm in order to obtain the records. Upon arriving I showed my credentials to **(b)** (6) and **(b)** (6), (b) (4). The records for the nine infected patients were provided, but **(b)** (6) requested a receipt to prove that I had acquired the documents. After

approval from Supervisor Gorney, I provided a hand written note indicating I had acquired the patients' records. Please see Attachment # 11 for the hand written note. Upon my departure from (b) (4) I left the box of office paper as instructed.

On July 26, 2011 Investigator McNeill and I visited (b) (4) also known as according to Walgreens, and spoke with (b) (6), (b) (4) Administrator. (b) (6), (b) (4) indicated that she was notified of the issue on July 10, 2011 via a telephone message from Walgreens and received a recall notice on July 12, 2011, but complained that the recall notice did not provide good instructions. (b) (6), (b) (4) indicated that the firm had issues with tracing back the lot numbers with the syringes used because the syringes did not have the lot code on the syringe packages. Per the example she gave us, the outer package did not have the lot code but the inner packaging did have the lot code on it, please see Attachment # 12. (b) (6), (b) (4) did provide a list of patients that were injected with Avastin obtained from Walgreens from June 22, 2011 to July 11, 2011, please see Attachment # 13. (b) (6), (b) (4) stated that all patients on the list provided had checkups and only one patient presented with symptoms of an infection. (b) (6), (b) (4) provided that patient's medical record for the treatment through July 26, 2011 at their facility, but that the patient was referred to (b) (4) Also, (b) (4) sent three unused syringes of Avastin to (b) (4) for sterility testing. (b) (6), (b) (4) was aware that one syringe tested positive for contamination, one syringe tested negative, and one syringe she had no results for. She notified us that Holly Montejano from DOH had been in contact with her.

On July 27, 2011 I contacted (b) (4) via telephone in order to obtain the sterility report for the tested syringes and medical records for the patients' from (b) (4) (b) (6), (b) (4) provided the contact information Microbiologist, and (b) (6), (b) (4) Ophthalmologist. While trying to get into contact with (b) (6), (b) (4) I spoke with (b) (6), (b) (4) Laboratory Technician, who explained to me that was currently on vacation. She went on to explain that (b) (6), (b) (4) had provided the information to the Miami-Dade Health Department. The contacts at the location to which the reports were sent are (b) (6), (b) (4) and (b) (6), (b) (4) This information was provided to management. I attempted to contact (b) (6), (b) (4) and in the course of doing so spoke with (b) (6), (b) (4) She explained to me that (b) (6), (b) (4) was on vacation and that the medical records would have to be obtained from the Medical Records an ophthalmologist who has seen the (b) (4) patient, called me. He Department. (b) (6), (b) (4) explained to me that he has seen the patient, but that (b) (6), (b) (4) is the physician of record. (b) (6), (b) (4) also explained that (b) (4) has not prescribed any treatment different from her doctors at (b) (4) He went on to say that he believes that the patient's vision is permanently damaged. I contacted the Medical Records Department and spoke with (b) (6), (b) (4) she stated that she would not be able to release the records without the patient's signature. I explained to (b) (6), (b) (4) the applicable regulations and laws that give FDA the authority to obtain the medical records in question without the patient's signature. She indicated that this would have to be handled by individuals higher up and to fax the information over.

On July 29, 2011 I visited (b) (4) and obtained medical records. I met with (b) (6), (b) (4) Chief Nursing Officer, and (b) (6), (b) (4) Executive Director of Quality Management. (b) (6), (b) (4) spoke with (b) (6), (b) (4) Interim Privacy Officer, who requested a signed document from FDA requesting the information. I informed (b) (6), (b) (4) that FDA is not required to provide such documentation; I did offer her an unsigned form FDA 461 with the patient in question's name. (b) (6), (b) (4) agreed this would be acceptable and that (b) (6), (b) (4) would provide the documentation I requested. (b) (6), (b) (4) also examined nine other patients linked to this outbreak and subsequently provided the names of these patients. I amended the form FDA 461 to include the names of the additional nine individuals. (b) (6), (b) (4) explained that the (b) (4) patient had an incomplete

medical record because a proper medical file was not created on the first visit; this led to documents from that visit to disappear. She indicated that they were in the process of trying to track down the missing documents. I received all the medical records for the patients that were seen by (b) (4) (b) (6), (b) (4) Administrative Assistant, explained to me that the copies provided do not include the ultrasounds, because of the recording materials inability to be photocopied with clarity.

On August 8, 2011 I contacted **(b)** (6), (b) (4) in order to obtain results from **(b)** (6), (b) (4) culture results from nine separate patients with known infections and five unused syringes. All nine of the patients' cultures were positive for *Streptococcus mitis/ oralis*. The lot number used on these patients was 07062011. As for the syringes all three syringes of lot 07062011 were positive for *Streptococcus mitisi/ oralis*. Lot 06222011 showed no growth; while lot 07012011 was positive for *Streptococcus mitis/ oralis*. Please see Attachment # 14 for a copy of **(b)** (6), (b) (4) culture report.

For a summary of Avastin lots and infections by clinics, please see Attachment # 15.

Per request from OEO, the medical records were sent directly to CDER's Office of New Drugs, Dr. Wiley A. Chambers, without being photocopied or included as an exhibit in this memo.

On August 16, 2011, two syringes were collected from DOH. These syringes were apart of a sample collection they had conducted. That sample collection was sent to CDC from analysis, but the two syringes obtained from DOH were not analyzed. The sample number for these two syringes is INV 601149.

Attachments

- 1. **(b)** (4) Medical Invoice documenting the sale of Avastin to Walgreens (3 pgs)
- 2. Walgreens Pick-up/ Delivery Slips for InfuPharma and eye clinics (11 pgs)
- 3. Contract between Walgreens and InfuPharma (2 pgs)
- 4. Drug Recall Notices dated July 11, 2011 and July 15, 2011 (2 pgs)
- 5. Avastin Lots Prepared (1 pg)
- 6. Avastin Orders (6 pgs)
- 7. Avastin MD Distribution List (1 pg)
- 8. Signed Affidavit copy (1 pg)
- 9. **(b) (4)** Avastin Injection List (28 pgs)
- 10. Avastin Injection Procedure (1 pg)
- 11. Hand Written Receipt Note to (b) (4) (1 pg)
- 12. Photocopy of Avastin Labeling from Walgreens at (b) (4) (1 pg)
- 13. (b) (4) Patient Summary of Avastin from Walgreens (1 pg)
- 14. (b) (4) Patient and Avastin Culture Results (1 pg)

15. Avastin Lot Flow Chart (1 pg)

Craig A. Garmendia, CSO

MIA-RP Domestic Operations

Kelly M. McNeill, CSO

MIA-RP Domestic Operations

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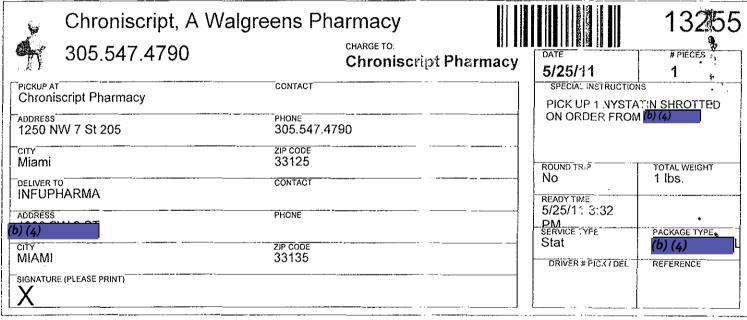
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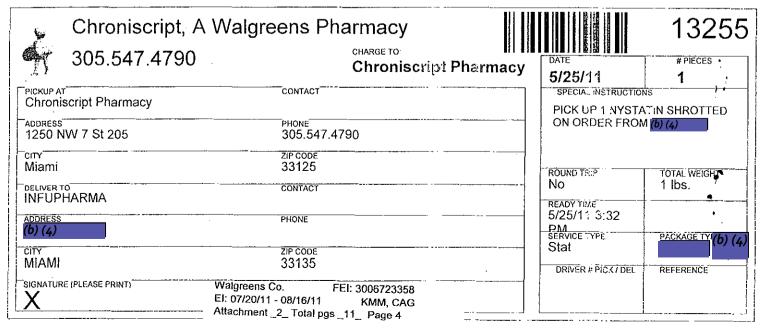
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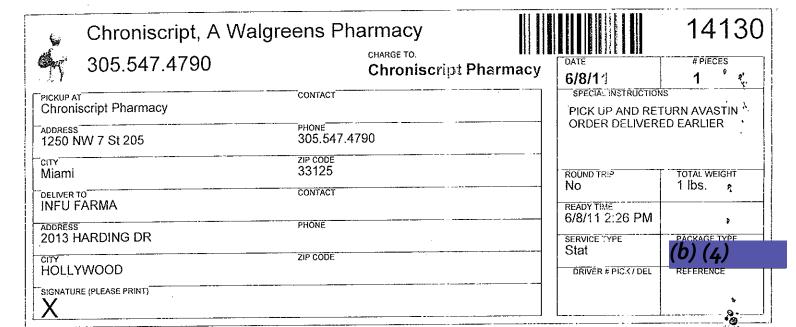
Attachment _2_ Total pgs _11_ Page 5

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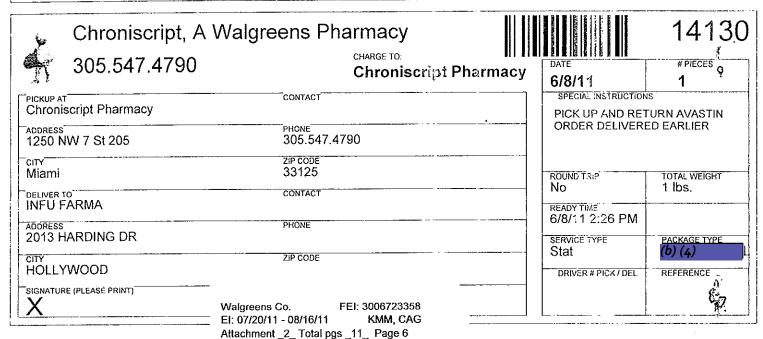
PIECES

6/8/11 SPECIAL INSTRUCTIONS PICK UP AVASTING AT CHRONISCRIPT AND DELIVER TO HOLLYWOOD. RETURN WITH NEW AVASTIN INJECTABLES

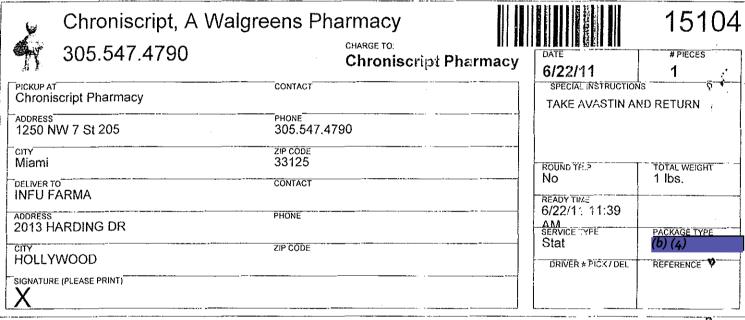
ROUND TRIP	TOTAL WEIGHT 1 lbs.
READY TIME 6/8/11 10:29	-
AM SERVICE TYPE	
SERVICE TYPE Stat	PACKAGE TYPE (b) (4)
DRIVER # PICK / DEL	REFERENCE

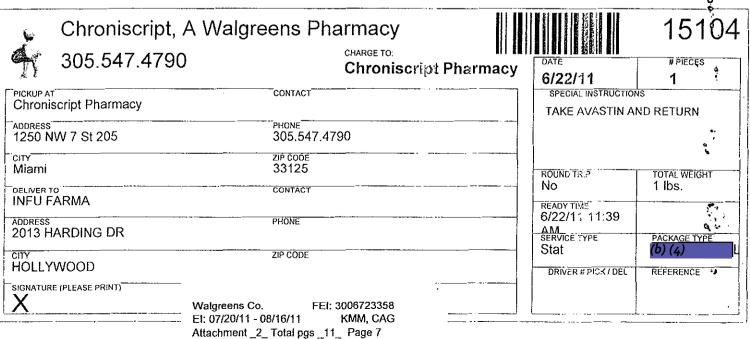


Chroniscript, A Walgreens Pharmacy CHARGE TO: 305.547.4790 # PIECES Chroniscript Pharmacy 6/8/11 1 SPECIAL INSTRUCTIONS CONTACT Chroniscript Pharmacy PICK UP AND RETURN AVASTIN ORDER DELIVERED EARLIER PHONE 305.547.4790 1250 NW 7 St 205 ZIP CODE 33125 Miami TOTAL WEIGHT ROUND TRIP No 1 lbs. CONTACT DELIVER TO **INFU FARMA** READY TIME 6/8/11 2:26 PM AODRESS PHONE 2013 HARDING DR SERVICE TYPE PACKAGE TYP Stat ZIP CODE HOLLYWOOD DRIVER # PICK / DEL SIGNATURE (PLEASE PRINT)



Chroniscript, A Walg	greens Pharmacy		15104
305.547.4790	charge to: III III III III Chroniscript Pharmacy	DATE 6/22/11	# PIECES &
Chroniscript Pharmacy	CONTACT	SPECIAL INSTRUCTION TAKE AVASTIN AT	· ·
ADDRESS 1250 NW 7 St 205	PHONE 305.547.4790		
Miami	ZIP CODE 33125	ROUND TRIP	TOTAL WEIGHT
DELIVER TO INFU FARMA	CONTACT	No READY TIME	1 lbs.
ADDRESS 2013 HARDING DR	PHONE	6/22/11 11:39 AM SERVICE TYPE	PACKAGE TYPE
HOLLYWOOD	ZIP CODE	Stat ORIVER # PICK / DEL	(b) (4) REFERENCE
SIGNATURE (PLEASE PRINT)			





Chroniscript, A Walgreens Pharmacy

305.547.4790

Chroniscript Pharma

PICKUP AT INFU FARMA	CONTACT	
ADDRESS 2013 HARDING ST	рноме 954-923-3839	
CITY HOLLYWOOD	ZIP CODE 33020	
DELIVER TO Chroniscript Pharmacy	CONTACT	
address 1250 NW 7 St 205	PHONE 305.547.4790	
cny Miami	zip code 33125	

	Distriction of the control of the co
	DATE
асу	7/1/11

15785

PIECES %

SPECIAL INSTRUCTIONS

PICK UP MEDS AND DELIVER TO CHRONISCRIPT TODAY.

TOTAL WEIGHT ROUND TRIP No 1 lbs. READY TIME

7/1/11 4:13 PM SERVICE TYPE Stat

DRIVER # PICK / DEL

(b) (4) REFERENCE

PACKAGE TYPE



Chroniscript, A Walgreens Pharmacy

305.547.4790

CHARGE TO:

Chroniscript Pharmacy

÷ 1	Chromschiperhalmacy		
PICKUP AT INFU FARMA	CONTACT		
ADDRESS 2013 HARDING ST	PHONE 954-923-3839		
HOLLYWOOD	ZIP CODE 33020		
DELIVER TO Chroniscript Pharmacy	CONTACT		
ADDRESS 1250 NW 7 St 205	PHONE 305.547.4790		
CITY Miami	ZIP CODE 33125		
SIGNATURE (PLEASE PRINT)			

		Personal State of Sta		CHONON CONTRACTOR	
 	Γ	DA	ΤE		

15785

PIECES*

7/1/11 SPECIAL INSTRUCTIONS

PICK UP MEDS AND DELIVER TO CHRONISCRIPT TODAY.

ROUND TRIP No READY TIME 7/1/11 4:13 PM

SERVICE TYPE Stat

PACKAGE TYPE (b) (4)

TOTAL WEIGHT

1 lbs.

DRIVER # PICK / DEL REFERENCE



Chroniscript, A Walgreens Pharmacy

305.547.4790

niscript Pharm

ふず	Chromscript Pha	armac
PICKUP AT INFU FARMA	CONTACT	·
ADDRESS 2013 HARDING ST	PHONE 954-923-3839	
HOLLYWOOD	ZIP CODE 33020	
Chroniscript Pharmacy	CONTACT	
ADDRESS 1250 NW 7 St 205	PHONE 305.547.4790	
city Miami	ZIP CODE 33125	
SIGNATURE (PLEASE PRINT)	Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment _2 _ Total pgs _11 _ Page 8	



15785

PIECES

SPECIAL INSTRUCTIONS

PICK UP MEDS AND DELIVER TO CHRONISCRIPT TODAY.

TOTAL WEIGH. ROUND TR.P

No READY TIME 7/1/11 4:13 PM

SERVICE TYPE

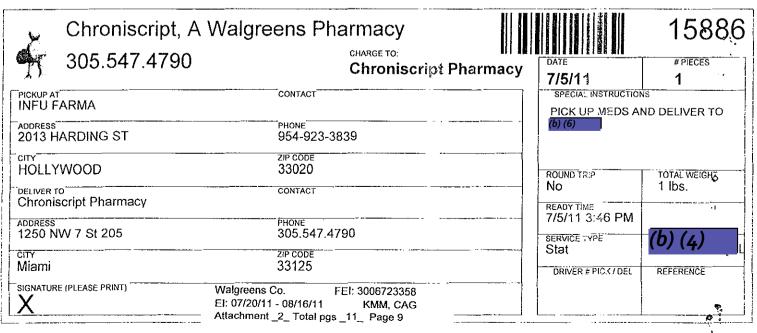
PACKAGE TYPE Stat

1 lbs.

REFERENCE . DRIVER # PICK / DEL

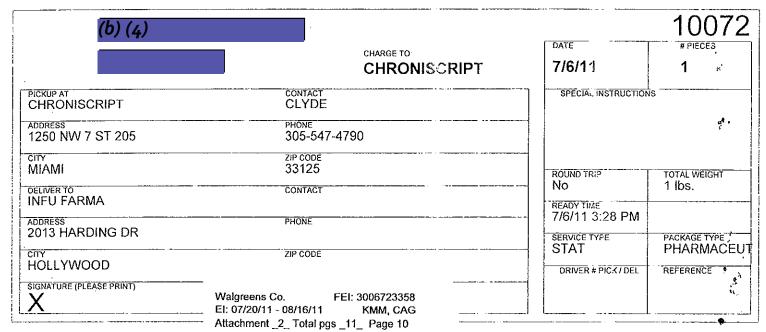
15886 Chroniscript, A Walgreens Pharmacy CHARGE TO: 305.547.4790 **Chroniscript Pharmacy** 7/5/11 CONTACT SPECIAL INSTRUCTIONS INFU FARMA PICK UP MEDS AND DELIVER PO ADDRESS 2013 HARDING ST 954-923-3839 ZIP CODE HOLLYWOOD 33020 TOTAL WEIGH ROUND TRIP No 1 lbs. CONTACT DELIVER TO Chroniscript Pharmacy READY TIME 7/5/11 3:46 PM PHONE 1250 NW 7 St 205 305.547.4790 SERVICE TYPE (b) (4) Stat ZIP CODE 33125 Miami DRIVER # PICK / DEL REFERENCE SIGNATURE (PLEASE PRINT)

15886 Chroniscript, A Walgreens Pharmacy 305.547.4790 # PIECES Chroniscript Pharmacy 7/5/11 SPECIAL INSTRUCTIONS CONTACT **INFU FARMA** PICK UP MEDS AND DELIVER TO (b) (6) PHONE 2013 HARDING ST 954-923-3839 **HOLLYWOOD** 33020 TOTAL WEIGHO ROLIND TRIP No 1 lbs. DELIVER TO Chroniscript Pharmacy READY TIME 7/5/11 3:46 PM ADDRESS 1250 NW 7 St 205 305.547.4790 SERVICE TYPE (b) (4) Stat ZIP CODE 33125 Miami DRIVER # PICK/ DEL REFERENCE SIGNATURE (PLEASE PRINT)



(b) (4)			10072
	CHARGE TO: CHRONISCRIPT	7/6/11	# PIECES •
PICKUP AT CHRONISCRIPT	CONTACT CLYDE	SPECIAL INSTRUCTION	is
ADDRESS 1250 NW 7 ST 205	рноме 305-547-4790		.
MIAMI	ZIP CODE 33125	ROUND TRIP	TOTAL WEIGHT
DELIVER TO INFU FARMA	CONTACT	READY TIME 7/6/11 3:28 PM	. 103.
ADDRESS 2013 HARDING DR	PHONE	SERVICE TYPE STAT	PACKAGE TYPE PHARMACEUT
HOLLYWOOD	ZIP CODE	DRIVER # PICK / DEL	REFERENCE
SIGNATURE (PLEASE PRINT)			<u> </u>

(b) (4)	CHARGE TO:	DATE	10072
	CHRONISCRIPT	7/6/11	1 💃
PICKUP AT CHRONISCRIPT	CONTACT CLYDE	SPECIAL INSTRUCTION	s
AODRESS 1250 NW 7 ST 205	PHONE 305-547-4790		**
MIAMI	ZIP CODE 33125	ROUND TRIP	TOTAL WEIGHT
DELIVER TO INFU FARMA	CONTACT	READY TIME	1 lbs.
ADDRESS 2013 HARDING DR	PHONE	7/6/11 3:28 PM SERVICE TYPE	PACKAGE TYPE
CITY HOLLYWOOD	ZIP CODE	STAT DRIVER # PICK/ DEL	PHARMACEU REFERENCE
SIGNATURE (PLEASE PRINT)		-	
^			



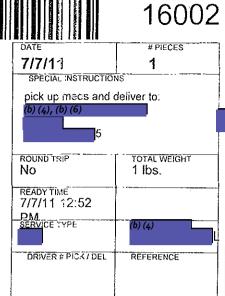


Chroniscript, A Walgreens Pharmacy

305.547.4790

Chroniscript Pharmacy

	Om om output	
PICKUP AT INFU FARMA	CONTACT	
address 2013 HARDING ST	PHONE 954-923-3839	
CITY HOLLYWOOD	ZIP CODE 33020	
DELIVER TO Chroniscript Pharmacy	CONTACT	
NODRESS 1250 NW 7 St 205	PHONE 305.547.4790	
ony Miami	ZIP CODE 33125	





Chroniscript, A Walgreens Pharmacy

305 547 4700

CHARGE TO:

1	Chroniscript Pharmacy
PICKUP AT INFU FARMA	CONTACT
ADDRESS 2013 HARDING ST	рноме 954-923-3839
HOLLYWOOD	ZIP CODE 33020
Chroniscript Pharmacy	CONTACT
ADDRESS 1250 NW 7 St 205	PHONE 305.547.4790
CITY Miami	ZIP CODE 33125
SIGNATURE (PLEASE PRINT)	

PIECES 7/7/11 SPECIAL INSTRUCTIONS pick up mecs and deliver to: ROUND TR.P TOTAL WEIGHT No 1 lbs. READY TIME 7/7/11 12:52 PM SERVICE TYPE PACKAGE TYPE Stat (b) (4) DRIVER # PICK / DEL REFERENCE



Chroniscript, A Walgreens Pharmacy

305.547.4790

Chroniscript Pharmacy

CONTACT **INFU FARMA** ADDRESS PHONE 2013 HARDING ST 954-923-3839 ZIP CODE **HOLLYWOOD** 33020 DELIVER TO CONTACT Chroniscript Pharmacy 1250 NW 7 St 205 305.547.4790 ZIP CODE 33125 Miami SIGNATURE (PLEASE PRINT) Walgreens Co. FEI: 3006723358 El: 07/20/11 - 08/16/11 KMM, CAG

Attachment _2_ Total pgs _11_ Page 11

16002

PIECES

16002

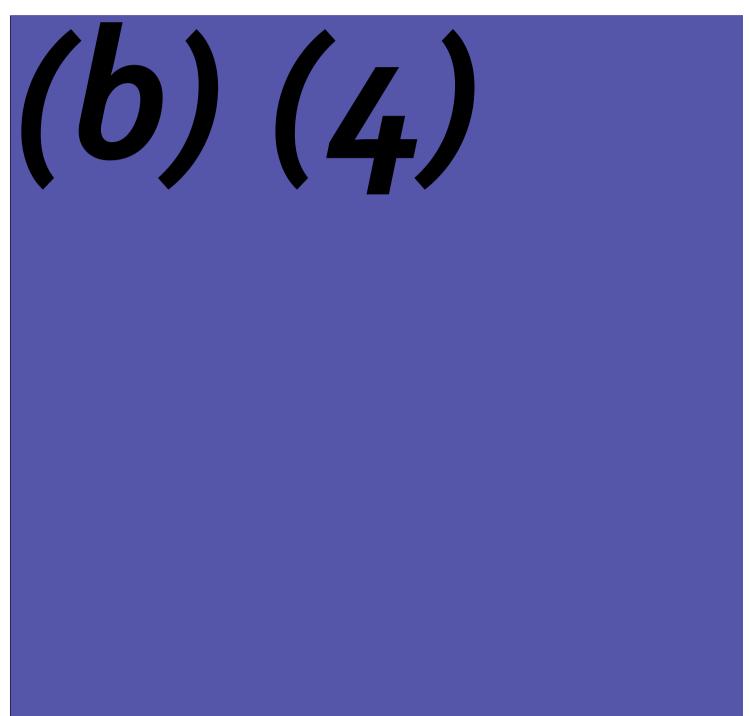
SPECIAL INSTRUCTIONS

pick up mecs and deliver to:

	ą.
ROUND TR.	TOTAL WEIGHT
No	1 lbs.
	·
READY TIME	- *
7/7/11 12:52	
PM	
SERVICE TYPE	PACKAGE TYPE
Stat	(b) (4)
DRIVER # PICK / DEL	REFERENCE

AMENDMENT TO PHARMACY SERVICES AGREEMENT

THIS AMENDMENT TO PHARMACY SERVICES AGREEMENT (this "Amendment") is entered into effective as of the _____ day of April, 2011, by and between InfuPharma LLC ("InfuPharma"), a Florida limited liability company, and Talanco One, Inc. d/b/a Chroniscript, a Florida corporation ("Chroniscript").



Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment _3_ Total pgs _2_ Page 1



INFL	PHA	$\mathbf{R}\mathbf{M}$	A LL
		-	

Printed Name:__

TALANCO ONE, INC. d/b/a CHRONISCRIPT

Walgreens Co. El: 07/20/11 - 08/16/11 KMM, CAG Attachment _3_ Total pgs _2_ Page 2

FEI: 3006723358

URGENT: DRUG RECALL

July, 11 2011

Re: AVASTIN

Package Size: .10ML Injection Lot Number: 06222011 - 07072011

Dear Customer:

Chror iscript Pharmacy is recalling AVASTIN - .10ml Injection Lots number 06222011 through 07072011. This lot is being recalled because it is suspect in contamination.

Please examine your inventory immediately and DO NOT USE. Call us at 305-547-4790 to arrange return all units of AVASTIN - .10ml Injection Lots number 06222011 through 07072011.

Stop distributing and immediately quarantine the referenced lot number only. Please carry out a physical count and record this data.

Thank you for your cooperation.

We appreciate your immediate attention and cooperation. Chroniscript Pharmacy remains committed to product quality, integrity, and patient satisfaction and we sincerely regret any inconvenience this action may cause.

URGENT: DRUG RECALL

July, 15 2011

Re: AVASTIN RECALL (EXPANDED)

Package Size: .10ML Injection

Lot Number: ALL

Dear Customer:

The Florida Department of Health has requested an expanded recall of AVASTIN injection syringes dispensed by Chroniscript pharmacy. Chroniscript requests that ANY and EVERY AVASTIN syringe that might be in your practice be removed from use and contact us for further instructions.

Please examine your inventory immediately and DO NOT USE. Call us at 305-547-4790 to arrange return all units of **AVASTIN**.

Stop distributing and immediately quarantine the referenced Avastin. Please carry out a physical count and record this data.

Thank you for your cooperation.

We appreciate your immediate attention and cooperation. Chroniscript Pharmacy remains committed to product quality, integrity, and patient satisfaction and we sincerely regret any inconvenience this action may cause.

Avastin Lots Prepared

Lot Date	Lot Number	Units In Lot	Avatin Lot	Avastin Exp.
5/5/2011	5052011	11	878460	6/30/2012
5/11/2011	5112011	26	878463	6/30/2012
5/25/2011	5/25/2011	60	852712	4/30/2012
6/8/2011	6082011	48	878460	6/30/202
6/21/2011	6212011	16	879296	7/30/2012
7/1/2011	7012011	4	879296	7/30/2012
7/5/2011	7052011	30	879296	7/30/2012
7/6/2011	7062011	15	879296	7/30/2012

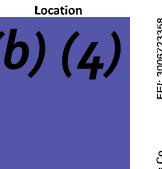
Avastin Orders

Γ	Customer Name	Disp Date	RX No
		4-May-11	124705
(b) (4), (b)	(b) (6)	4-May-11	124704
(0) (4), (0)	(D)	4-May -11	124690
		4-May-11	124700
		4-May-11	124696
		4-May-11	124629
		4-May-11	124701
		4-May-11	124649
		4-May-11	124699
		4-May-11	124698
		4-May-11	124702
		4-May-11	124707
		5-May -1 1	124881
		10-May -1 1	125397
		10-May -1 1	125370
		11-May-11	125383
		11-May-11	125386
		′ 11-May-11	125390
		11-May -1 1	125385
		1 1- May-11	125399
		11-May - 11	125397
		11-May - 11	125384
		11-May-11	125403
		11-May - 11	125409
		11-May - 11	125387
		11-May-11	125392
		11-May-11	125394
		11-May - 11	125396
		11-May-11	125388
		11-May-11	125370
		11-May-11	125374
		11-May- 1 1	125371
		11-May-11	125375

Do	ctor
(b) (4), (b) (6)

Date of Delivery		
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5/12/2011



Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment _6_Total pgs _6_ Page 1

125376	11-May-11
125406	11-May-11
126170	12-May-11
126179	17-May-11
126169	17-May-11
126167	17-May-11
126177	17-May-11
126174	17-May-11
126168	17-May-11
126176	17-May-11
125995	17-May-11
126294	18-May-11
126378	18-May-1 1
126293	18-May-11
126278	18-May-11
126252	18-May-11
126260	18-May-11
126291	18-May-11
126378	19-May-11
126779	23-May - 11
125389	24-May-11
126984	24-May-11
124693	24-May-11
126987	24-May-11
127236	24-May-11
126988	24-May-11
126875	24-May -1 1
127235	25-May-11
127277	25-May-11
127214	25-May-11
124693	25-May-11
127231	25-May-11
127189	25-May-11
127247	25-May-11
127187	25-May-11
127246	25-May-11
127209	25-May-11
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(b) (4), (b) (6)

5/12/2011
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26-May
26-May

26-May 26-May (b) (4)

Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment _6_ Total pgs _6_ Page 2

(b) (4)

127217	25-May-11
127236	25-May-11
127207	25-May-11
127210	25-May-11
127212	25-May-11
125395	25 - May-11
127225	25-May-11
127199	25-May-11
127213	25-May-11
127234	25-May-11
127185	25-May-11
127184	25-May-11
127193	25-May-11
127228	25-May-11
127249	25-May-11
127257	25-May-11
127262	25-May-11
127272	25-May-11
126828	26-May-11
101628	27-May-11
127572	27-May-11
125391	27-May-11
127573	27-May-11
127574	27-May-11
127592	31-May-11
127815	1-Jun-11
127817	1-Jun-11
127832	1-Jun-11
128423	7-Jun-11
128426	7-Jun-11
128352	7-Jun-11
128346	7-Jun-11
128427	7-Jun-11
128347	7-Jun-11
128350	7-Jun-11
128546	8-Jun-11
128551	8-Jun - 11

(b)	(6)	(b) (6), (b) (4)
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26-May
26-May
2-Jun
1-Jun
2-Jun
9-Jun

128424	8-Jun-11		
127218	8-Jun-11	(b) (6), (b) (4)	
127237	8-Jun-11	(-) (-) (-) (4)	
128536	8-Jun-11		
128537	8-Jun-11		(b) (b
128539	8-Jun-11		,
126286	9-Jun-11		
128680	9-Jun-11		
128690	9-Jun-11		
128689	9-Jun-11		
128740	9-Jun-11		
128686	9-Jun-11		
128688	9-Jun-11		
128676	9-Jun-11		
128733	9-Jun-11		
128841	10-Jun-11		
128794	10-Jun-11		
128828	10-Jun-11		
128872	10-Jun-11		
128873	10-Jun-11		
128981	13-Jun-11		
128983	13-Jun-11		
128977	13-Jun-11		
128980	13-Jun-11		
128976	13-Jun-11		
129332	14-Jun-11		
129161	14-Jun-11		
129338	15-Jun-11		
129331	15-Jun-11		
129330	15-Jun-11		
129339	15-Jun-11		
129367	15-Jun-11		
129181	15-Jun-11		
129371	15-Jun-11		
129474	16-Jun-11		
129471	16-Jun-11		
129959	20-Jun-11		

9-Jun 9-Jun Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment _6_ Total pgs _6_ Page 4 9-Jun 9-Jun 9-Jun 9-Jun 10-Jun 14-Jun 10-Jun 10-Jun 10-Jun 13-Jun 13-Jun 13-Jun 13-Jun 13-Jun 14-Jun 14-Jun 15-Jun 15-Jun 15-Jun 15-Jun 15-Jun 15-Jun 15-Jun 16-Jun 16-Jun 24-Jun

20-Jun-11
21-Jun-11
22-Jun-11
01-Jul-11
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01-Jul-11
05-Jul-11
05-Jul-11
05-Jul-11
05-Jul-11
06-Jul-11

161	161
(U)	(0)

(b) (6), (b) (4)



(b) (4)

Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment _6_Total pgs _6_ Page 5

131401	06-Jul-11	(b)(6)	
131424	06-Jul-11		
131394	06-Jul-11		
131417	06-Jul-11		
131414	06-Jul-11		
131383	06-Jul -1 1		
131393	06-Jul-11		
131400	06-Jul-11		
131392	06-Jul-11		
131402	06-Jul-11		
131395	06-Jul-11		
131389	06-Jul-11		
131398	06-Jul -1 1		
131388	06-Jul-11		
131416	06-Jul-11		
131384	06-Jul-11		
131419	06-Jul-11		
131467	06-Jul -11		
131472	06-Jul-11		
131552	07-Jul-11		
131563	07-Jul-11		
131551	07-Jul-11		
131555	07-Jul-11		
131554	07 - Jul-11		
131553	07-Jul-11		
131556	07-Jul-11		
131561	07-Jul-11		
131665	07-Jul-11		
131558	07-Jul-11		
131548	07-Jul-11		
131549	07-Jul-11		
131562	07-Jul-11		
131560	07-Jul-11		

7-Jul
7-Jul
6-Jul
6-Jul
8-Jul

(b)	(4)

Walgreens Co. FEI: 3006723358 EI: 07/20/11 - 08/16/11 KMM, CAG Attachment_6_Total pgs_6_ Page 6 (b) (6), (b) (4)

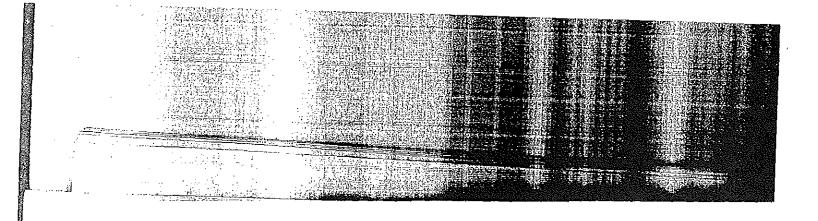
AFFIDAVI	r	SAMPLE NO. DOC 679739
STATE OF	COUNTY OF	500077.07
Florida Kally M M Neill and Cook A Cook	Miami-Dade	
Before me, Kelly M. McNeill and Craig A. Garmend Services, Food and Drug Administration, designated but Large 803; Reorganization Plan No. IV, Secs. 12-15 effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 or take oaths, affirmations, and affidavits, personally at the county and state aforesaid, who, being duly sworn,	by the Secretary, under authority of the Acts, effective June 30, 1940; Reorganization Statutes at Large 965 (20 U.S.C. 3508) efgepeared Eduardo (NMI) Ruiz	ct of January 31, 1925, 43 Statutes 1 Plan No. 1 of 1953, Secs. 1-9,
I am the General Manager of Walgreen's Ph knowledge of the firm's receipt, storage, and Manager at Chronoscipt since 2005. When O I continued to hold the same position.	d delivery of Avastin. I have held	the position of General
On 5/31/11, my firm received 4 - 100MG vi		rom (b) (4) hipment was delivered to
my firm, and is documented by Invoice #120 Lading. This shipment was sent to Infuphar reconstituted Avastin in syringes packaged in 7/7/11. The corresponding lots assigned to the and 7072011, respectively. However, documented to dates as 6/21/2011 and 7/6/2011.	010189133, dated 5/31/11. This is ma of Hollywood, FL in sealed bin sealed bags from this lot on 6/2 the syringes by Infupharma are 62 nentation provided to Walgreen's	invoice acts as a Bill of bags. My firm received 22/11, 7/1/11, 7/5/11, and 222011, 7012011, 7052011, as by Infupharma shows the
I verified and provided the following docum Invoice #12010189133, dated 5/31/11, Invoidated 7/5/11, the pharmacy agreement betwee Avastin, Avastin patient information, shipment shipment documentation of reconstituted Av. 7/6/11, and the two recall notices of Avastin adverse reactions to Avastin on 7/10/11. Was a phone call from a physician whose patient I have received 12 reports of infection from	vice #12010173806, dated 5/11/11 reen Walgreen's and Infupharma, ent documentation of bulk Avastivastin from Infupharma to Chronic dated 7/11/11 and 7/15/11. My ayne Talamas, Pharmacy Manage who took Avastin and consequent Avastin patients from physicians	1, Invoice #12010218946, the distribution list of in vials to Infupharma and discript from 5/5/11 through firm first became aware of the of Chroniscript received antly became infected.
I vend this statement a	I accumentedge th	I 16 true.
AFFIANT'S SIGNATURE AND TITLE	1.	<u> </u>
	eneral Algo	
FIRM'S NAME AND ADDRESS (Include ZIP Code) Walgreen's Pharmacy DBA Chroniscript 1250 NW 7th S	St. Ste 205 Miami, FL 33136	
Subscribed and sworn to before me at	Miami, Florida	
this 21st day of July	, 2011 (City and State)	
	Killy M. M. Dull (Employee's S.	· · · · · · · · · · · · · · · · · · ·
Employee of the Department of Health and Human Service June 30, 1940; Reorganization Plan No. 1 of 1953, effective		

All Avastin 6-20 through 7-6-2011 To Date From 6/20/2011 to 7/6/2011

(*b*) (*6*), (*b*) (*4*) 07/13/2011 1:57 PM

E/I	Dt of Svc	Name	Narrative	Eye	Lot#	Exp Date	Drug Pharmacy	visit
			(b) (4)					
686191 06	5/23/2011		Avastin 1.25mg ndc#50242-0060-01	os	06222011	7/22/2011	(b) (4)/Chroniscript	<u> </u>
686125 06	5/23/2011	,	Avastin 1.25mg ndc#50242-0060-01	OD	06222011	7/22/2011	(b) (4)/Chroniscript	
686217 06			Avastin 1.25mg ndc#50242-0060-01	ΟU	06222011	7/22/2011	(b) (4)/Chroniscript	
686152 06	5/23/2011		Avastin 1.25mg ndc#50242-0060-01	os	06222011	7/22/2011	(b) (4)/Chroniscript	
686210 06	5/23/2011		Avastin 1.25mg ndc#50242-0060-01	ΟU	06222011	7/22/2011	(b) (4)/Chroniscript	
686136 06	5/23/2011		Avastin 1.25mg NDC#50242-0060-01	os	06212011	7/21/2011	(b) (4)/Chroniscript	
686197 06	3/23/2011		Avastin 1.25mg ndc#50242-0060-01	OD	06222011	7/22/2011	(b) (4)/Chroniscript	
686128 06	3/23/2011		Avastin 1.25mg ndc#50242-0060-01	os	06212011	7/21/2011	(b) (4)/Chroniscript	
686117 06	3/23/2011		Avastin 1.25mg ndc#50242-0060-01	os	06212011	7/21/2011	(b) (4)(Chroniscript	
686114 06	3/23/2011	·	Avastin 1.25mg ndc#50242-0060-01	os	06212011	6/21/2011	(b) (4)/Chroniscript	
686119 06			Avastin 1.25mg ndc#50242-0060-01	os	06212011	7/21/2011	(b) (4)/Chroniscript	
686209 06			Avastin 1.25mg ndc#50242-0060-01	OS	06212011	7/21/2011	(b) (4)/Chroniscript	
686198 06			Avastin 1.25mg ndc#50242-0060-01	OD	06212011	7/21/2011	(b) (4)/Chroniscript	
686140 06			Avastin 1.25mg ndc#50242-0060-01	os	06222011	7/22/2011	(b) (4)/Chroniscript	
686132 06			Avastin 1.25mg ndc#50242-0060-01	OD	06222011	7/22/2011	(b) (4)/Chroniscript	
686130 06			Avastin 1.25mg ndc#50242-0060-01	os	06222011	7/31/2011	(b) (4)/Chroniscript	
686133 06			Avastin 1.25mg ndc#50242-0060-01	OD	06222011	7/22/2011	(b) (4)/Chroniscript	
686139 06			Avastin 1.25mg ndc#50242-0060-01	OU	06222011	7/22/2011	(b) (4) Chroniscript	
686118 06			Avastin 1.25mg ndc#50242-0060-01	OS	0622/2011	7/22/2011	(b) (4)/Chroniscript	
686116 06			Avastin 1.25mg ndc#50242-0060-01	OD	06212011	7/21/2011	(b) (4)/Chroniscript	
686212 06		<u>r</u>	Avastin 1.25mg ndc#50242-0060-01	OU	06222011	7/22/2011	1 ^{(b) (4)} /Chroniscript	
686208 06			Avastin 1.25mg ndc#50242-0060-01	ΟU	06212011	7/21/2011	(b) (4):/Chroniscript	
686206 06			Avastin 1.25mg ndc#50242-0060-01	OD	06222011	7/22/2011	(b) (4)/Chroniscript	
686148 06	/23/2011		Avastin 1.25mg ndc#50242-0060-01	OD	06212011	7/21/2011	(b) (4)/Chroniscript	
is for								
1			<u>(b) (4)</u>					
) (4)			SR					
685575 06	/21/2011		Avastin 1.25mg ndc#50242-0060-01	OS	878463	6/30/2011	in house	
				777				tbs 7/14 a
688701 07	/05/2011		Avastin 1.25mg ndc#50242-0060-01	os	06212011	7/21/2011	Chroniscript	(b) (4)

Totals for **(b) (4)**TOTALS (26)



Appointments Listing (b) (4) Office

From 7/7/2011 to 7/7/2011

(b) (6), (b) (4)

<u> </u>	Pat Name	Lot Number	Exp date		Prepared by		vent	Referring
		7052011	8/5/2011			Avastin Inj	,	
	(b) (6), (b) (4)	7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011	Γ		Avastin Inj		
		7052011	8/5/2011	Γ		Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		*7062011	*8/6/2011			Avastin Inj		
		878460	6/30/2012			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011			Avastin Inj		
		7052011	8/5/2011	_		Avastin Inj		

(1) 00 = RIGHT EYE OS= LEPT EYE

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6/23/2011



(b) (6)

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PRIMARY EMPLOYER	SECONDARY EMPLOYER (if Applicable)
ADDRESS	ADDRESS
CITY, STATE ZIP	CITY, STATE ZIP
WORK PHONE	WORK PHONE
1	

NAME (Last, First Middle)	TION (if Different than above)	BIRTHDATE	LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY/BILLING ADDRESS (if	Applicable)		
CITY, STATE ZIP	CITY, STATE ZIP			
HOME PHONE	HOME PHONE			····· <u></u>
RELATIONSHIP TO PATIENT				

(b) (6)

SECONDARY INSURANCE (if Applicable)				
NAME OF INSURANCE COMPANY	POLICY#			
NAME OF INSURED	GROUP#			
ADDRESS OF INSURANCE COMPANY	COPAY AMT	COPAY AMT		
CITY, STATE ZIP	DEOUCTIBLE	DEDUCTIBLE		
RELATIONSHIP TO PATIENT	EFFECTIVE DAYE EXPIRATION	I DATE		

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PATIENT INFORMATION					
<i>(b)</i>	(6				
PRIMARY EMPLOYER	SECONDARY EMPLO	YER (if Applicable)			
ADDRESS	ADDRESS	<u> </u>			
CITY, STATE ZIP	CITY, STATE ZIP				
WORK PHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATION (if Diff NAME (Last, First Middle)	ferent than above)	SSN#	BIRTHDATE	LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY/BILLING	ADDRESS (if Applica	able)		
CITY, STATE ZIP	CITY, STATE ZIP				
HOME PHONE	HOME PHONE				
RELATIONSHIP TO PATIENT					
PRIMARY INSURANCE		POLIC	77. 10. 10. 10. 10. 10. 10. 10. 10. 10. 10		
<i>(b)</i>	(6				
SECONDARY INSURANCE (if Applicable) NAME OF INSURANCE COMPANY		POLI	(#35:00)		
NAME OF INSURED		GRO	UP#	······································	
ADDRESS OF INSURANCE COMPANY		COP	AY AMŢ		
CITY, STATE ZIP		DED	JCTIBLE		
RELATIONSHIP TO PATIENT		EFFE	CTIVE DATE	EXPIRATION DATE	· ·

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Walgreens Co. FEI: 3006723358
EI: 07/20/11 - 08/16/11 KMM, CAG
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PATIENT INFORMATION					
(b) (6)					
PRIMARY EMPLOYER	SECONDARY EMPLOY	/ER (if Applicable)			
AODRESS	ADDRESS				
CITY, STATE ZIP	CITY, STATE ZIP				
WORKPHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATION (if D	fferent than above)				
NAME (Last, First Middle)		SSN#	BIRTHDATE	LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY/BILLING	ADDRESS (if Applicable	0)	—.l	
CITY, STATE ZIP	CITY, STATE ZIP				
HOME PHONE	HOME PHONE				
RELATIONSHIP TO PATIENT					
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(b)	(6	5)			
SECONDARY INSURANCE (if Applicable) NAME OF INSURANCE COMPANY		POLICY	#		
NAME OF INSURED		GROUP	#		
ADDRESS OF INSURANCE COMPANY		COPAY	AMT		
CITY, STATE ZIP		DEDUC	TIBLE		
RELATIONSHIP TO PATIENT		EFFECT	TIVE DATE	EXPIRATION DAT	E

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	b) (8	5)			
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CITY, STATE ZIP	CITY, STATE ZIP				
WORK PHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATI NAME (Last, First Meddle)	ON (if Different than above)	SSN#	BIRTHDATE	LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY/BILLING	ADDRESS (if Applicable)			<u> </u>
CITY, STATE ZIP	CITY, STATE ZIP				
HOME PHONE	HOME PHONE	· · · · · · · · · · · · · · · · · · ·	,		
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ITY, STATE ZIP	CITY, STATE ZIP				
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OCAL ADDRESS	SECONDARY/BILLING	3 ADDRESS (if Applicable)			
CITY, STATE ZIP	CITY, STATE ZIP				
HOME PHONE	HOME PHONE				
RELATIONSHIP TO PATIENT					
PRIMARY INSURANCE		POLICY#			
SECONDARY INSURANCE (If Applications of insurance company)					
SECONDARY INSURANCE (If Applications of insured)		POLICY#			
SECONDARY INSURANCE (if Applic)		POLICY# GROUP#			

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(0)	U				
PRIMARY EMPLOYER	SECONDARY EMPLOYER	R (if Applicable)			
ADDRESS	ADDRESS				
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WORK PHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATION (if Differen NAME (Last, First Middle)	t than above)	SSN#	BIRTHDATE	LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY/BILLING A		BIACT TO THE	Ballondic	
CITY, STATE ZIP	CITY, STATE ZIP	SOLICO (II Pepsonolo)			
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PRIMARY INSURANCE NAME OF INSURANCE COMPANY		POLICY#			
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SECONDARY INSURANCE (if Applicable)		POLIÇY#			
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ADDRESS OF INSURANCE COMPANY		COPAY A	MT		
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RECATIONORIE TO PATIENT		2575011	TE UMIE	EXPIRATION DATE	

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RIMARY EMPLOYER	SECONDARY EMPLO	YER (if Applicable)			
DDRESS	ADDRESS				
ITY, STATE ZIP	CITY, STATE ZIP				
ORK PHONE	WORK PHONE			<u> </u>	
RESPONSIBLE PARTY INFORMATIO IAME (Last, First Middle)	N (if Different than above)	SSN# BIR	THDATE	LANGUAGE	SEX
OCAL ADDRESS	SECONDARY/BILLIN	G ADDRESS (if Applicable)			
CITY, STATE ZIP	CITY, STATE ZIP				
номе рноме	HOME PHONE				
RELATIONSHIP TO PATIENT				·	
PRIMARY INSURANCE		POLICY#			
(b) (l	6)	POLICY#			
NAME OF INSURANCE COMPANY		GROUP#			
NAME OF INSURANCE COMPANY NAME OF INSURED		GROUP#			
NAME OF INSURANCE COMPANY NAME OF INSURED ADDRESS OF INSURANCE COMPANY CITY, STATE ZIP					



AME (Last, First Middle)	MRN	ssn#	BIRTHDATE	LANGUAGE	SEX
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)) (E				
RIMARY EMPLOYER		MPLOYER (if Applicable)			
DDRESS	ADDRESS				
ITY, STATE ZIP	CITY, STATE ZI	iP 			
ORK PHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATION AME (Last, First Middle)	ON (if Different than abov	/e) ssn#	BIRTHDATE	LANGUAGE	SEX
OCAL ADDRESS	SECONDARY/BI	ILLING ADDRESS (if Applica	able)		
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OME PHONE	HOME PHONE				
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PRIMARY INSURANCE		POL	CY#		
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ME (Last, First Middle)	MRN	\$5N#	BIRTHDATE	LANGUAGE	SEX
	b) (<i>(6)</i>			
RIMARY EMPLOYER		EMPLOYER (if Applicable)			· ·
DORESS	ADDRESS				
ITY, STATE ZIP	CITY, STATE	ZIP			
NORK PHONE	WORK PHON	E			
RESPONSIBLE PARTY INFORMATION NAME (Last, First Middle)	DN (if Different than abo	ove) ssn#	BIRTHDATE	LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY	 BILLING ADDRESS (if Appli	cable)		
CITY, STATE ZIP	CITY, STATE	ZIP			
HOME PHONE	номе рном	É			
HOME PHONE RELATIONSHIP TO PATIENT	HOME PHON	£			· • • • • • • • • • • • • • • • • • • •
	номе рном		ICY#		
RELATIONSHIP TO PATIENT PRIMARY INSURANCE		POL	ICY#		
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PRIMARY INSURANCE NAME OF INSURANCE COMPANY SECONDARY INSURANCE (If Application of the insurance company)		POI POI GR	JCY# OUP#		

SIGNATURE OF PATIENT/GUARDIAN

DATE

Walgreens Co.

El: 07/20/11 - 08/16/11

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	MRN	SSN#	BIRTHDATE	LANGUAGE	SE:
b) (6)					
RIMARY EMPLOYER	SECONDARY EMPLO	OYER (if Applicable)			
DDRESS	ADDRESS				
TY, STATE ZIP	CITY, STATE ZIP				
ORK PHONE	WORK PHONE		· · · ·		
RESPONSIBLE PARTY INFORMATION AME (Last, First Middle)	DN (if Different than above)	55N#	BIRTHDATE	LANGUAGE	SE
DCAL ADDRESS	SECONDARY/BILLIN	G ADDRESS (if Applic	able)		
TY, STATE ZIP	CITY, STATE ZIP				
OME PHONE	HOME PHONE	•			
ELATIONSHIP TO PATIENT					
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PRIMARY INSURANCE		POL	ICY#		
SECONDARY INSURANCE (if Applic	able)	6 POL			
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PRIMARY INSURANCE PARE DE INSURANCE COMPANY SECONDARY INSURANCE (If Applications of insurance company NAME OF INSURANCE COMPANY ADDRESS OF INSURANCE COMPANY CITY, STATE ZIP	able)	POL GRO	ICY#	·	

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PATIENT INFORMATION AME (Last, First Middle)	MRN	*M2S	RIRTHDATE	LANGUAGE	SEX
(b) (6)					
RIMARY EMPLOYER	SECONDARY EM	IPLOYER (if Applicable)		,	
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	CITY, STATE ZIF				
ORK PHONE	WORK PHONE				
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	HOME PHONE				
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IOME PHONE		POLI	CY#		
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CONDARY EMPLOYER SECONDARY EMPLOYER (Happiscable) DDRESS ADDRESS ADDRESS ADDRESS CITY, STATE ZIP ORK PHONE WORK PHONE WORK PHONE WORK PHONE SESSONSIBLE PARTY INFORMATION (II Different than above) SSHP BIRTHOATE LANGUAGE SEX DEAL ADDRESS IF Applicable) ITY, STATE ZIP CITY, STATE ZIP CITY, STATE ZIP TOME PHONE HOME PHONE BLATIONSHIP TO PATIENT PRIMARY INSURANCE RANG OF INSURANCE COMPANY SECONDARY INSURANCE ADDRESS OF INSURANCE COMPANY POLICYP IAME OF INSURANCE COMPANY COPPAY AMT COPPAY AMT COPPAY AMT COPPAY AMT COPPAY AMT	PATIENT INFORMATION NAME (Last First Middle)	MRN	SSM#	RIRTHOATE	LANGUAGE	CEY
DURESS ADDRESS ADDRESS ITY, STATE ZIP CITY, STATE ZIP						
CITY, STATE ZIP CITY, STATE ZIP WORK PHONE WORK PHONE WESPONSIBLE PARTY INFORMATION (if Different than above) MESPONSIBLE PARTY INFORMATION (if Different than above) SSN# BIRTHOATE UNGUAGE SEX CITY, STATE ZIP CITY, S	PRIMARY EMPLOYER	SECONDARY EMPLOYER	R (if Applicable)			
RESPONSIBLE PARTY INFORMATION (if Different than above) AME (Last First Middle) CITY, STATE ZIP CITY, STATE ZIP CHORE PHONE ELATIONSHIP TO PATIENT PRIMARY INSURANCE AME OF INSURANCE COMPANY POLICYS SECONDARY INSURANCE COMPANY POLICYS FOUCH AME OF INSURANCE COMPANY COPAY AMT	ADDRESS	ADDRESS				
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AME (Last First Middle) SECONDARY/BILLING ADDRESS (If Applicable) SECONDARY/BILLING ADDRESS (If Applicable) SECONDARY/BILLING ADDRESS (If Applicable) ITY, STATE ZIP CITY, STATE ZIP COME PHONE ELATIONSHIP TO PATIENT POLICYS SECONDARY/INSURANCE ANE OF INSURANCE COMPANY POLICYS POLICYS POLICYS ADDRESS OF INSURANCE COMPANY COPAY AMT COPAY AMT COPAY AMT DEDUCTIBLE	WORK PHONE	WORK PHONE				
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SECONDARY INSURANCE (If Applicable) IAME OF INSURANCE COMPANY IAME OF INSURANCE COMPANY IAME OF INSURANCE COMPANY COPAY AMT CITY, STATE ZIP POLICY# CEDUCTIBLE	RELATIONSHIP TO PATIENT		<u>.</u>			
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DITY, STATE ZIP DEDUCTIBLE	NAME OF INSURED		GROUP#		<u></u>	
	ADDRESS OF INSURANCE COMPANY		COPAY A	мт		
RELATIONSHIP TO PATIENT EFFECTIVE DATE EXPIRATION DATE	CITY, STATE ZIP		ОЕФУСТІ	BLE		
	RELATIONSHIP TO PATIENT		EFFECTIV	E DATE	EXPIRATION DATE	

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PATIENT INFORMATION IAME (Last, First Middle)	MRN	SSN#	BIRTHOATE	LANGUAGE	SEX
(b) ((6)				
RIMARY EMPLOYER	SECONDARY EM	PLOYER (if Applicable)			
DDRESS	ADDRESS				
ITY, STATE ZIP	CITY, STATE ZIP				
VORK PHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATIO	N (if Different than above				
VAME (Last, First Middle)		SSN#	BIRTHDATE	LANGUAGE	SEX
OCAL ADDRESS	SECONDARY/BIL	LING ADDRESS (if Applicat	de)	<u> </u>	
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AME (Lest, First Middle)	l MRN	SSN#	BIRTHDATE	LANGUAGE	SEX
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HOME PHONE	HOME PHONE		-		
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ADDRESS OF INSURANCE COMPANY		COPAY A	MT		
CITY, STATE ZIP	·	DEDUCT	BLE		
RELATIONSHIP TO PATIENT		EFFECTI	VE DATE	EXPIRATION DATE	
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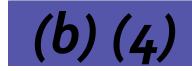
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06222011 7/22/2011



PATIENT INFORMATION WME (Last, First Middle)	MRN	lssn#	BIRTHOATE	LANGUAGE	SFX
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VORK PHONE	WORK PHONE				
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	i				
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(b) (<i>6)</i>				
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CITY, STATE ZIP	CITY, STATE ZIP				 ,
NORK PHONE	WORK PHONE				
RESPONSIBLE PARTY INFORMATIC VAME (Last, First Middle)	ON (if Different than above) 	BIRTHDATE	LANGUAGE	SEX
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PATIENT INFORMATION NAME (Last, First Middle)	MRN	SSN#	BIRTHDATE	LANGUAGE	SEX
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PRIMARY EMPLOYER	SECONDARY	EMPLOYER (if Applicable)			
ODRESS	ADDRESS		···		
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NORK PHONE	WORK PHONE	<u> </u>			
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SIGNATURE OF PATIENT/GUARDIAN

DATE

El: 07/20/11 - 08/16/11

Attachment _9_ Total pgs _28_ Page 23

FEI: 3006723358

KMM, CAG



ATIENT INFORMATION MF (Last First Middle)	IMRN	888#	BIRTHOATE	LANGUAGE] QEY
(b) (4)				
RIMARY EMPLOYER	SECONDARY E	MPLOYER (if Applicable)			
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OCAL ADDRESS	SECONDARY/B	ILLING ADDRESS (if Applica	bie)		
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OME PHONE	HOME PHONE				
ELATIONSHIP TO PATIENT					
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SECONDARY INSURANCE (If Appl	(6)				
IAME OF INSURANCE COMPANY		POLK	CY#		
AME OF INSURED		GROU	JP#		
DDRESS OF INSURANCE COMPANY		COPA	Y AMT		
CITY, STATE ZIP		DEOU	ICTIBL E		
CITY, STATE ZIP			CTIVE DATE	EXPIRATION DATI	
RELATIONSHIP TO PATIENT	2011 07/24 2011 07	EFFE	CTIVE DATE	EXPIRATION DATI	=

SIGNATURE OF PATIENT/GUARDIAN

DATE

Attachment _9_ Total pgs _28_ Page 24

FEI: 3006723358 KMM, CAG

NAME (Last, First Middle)	MRN	SSN#	BIRTHOATE	LANGUAGE	SEX
(b) (<i>(6)</i>				
PRIMARY EMPLOYER	SECONDARY EM	PLOYER (if Applicable)	············		
ADDRESS	ADDRESS		<u></u>		
CITY, STATE ZIP	CITY, STATE ZIP				
WORK PHONE	WORK PHONE		·		
RESPONSIBLE PARTY INFORMATION NAME (Last, First Middle)	ON (if Different than above	SSN#	BIRTHDATE	LANGUAGE	SEX
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CITY, STATE ZIP	CITY, STATE ZIP				
HOME PHONE	HOME PHONE				
RELATIONSHIP TO PATIENT					
PRIMARY INSURANCE NAME OF INSURANCE COMPANY		POLICY#			
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SECONDARY INSURANCE (If Applic	able)				
SECONDARY INSURANCE (If Applic	able)	POLICY#			
SECONDARY INSURANCE (If Applic) NAME OF INSURANCE COMPANY NAME OF INSURED	able)	POLICY# GROUP#			



PATIENT INFORMATION NAME (Last First Middle)	MBN	CCNA RIPT	HDATE LANGUAGE	QEY
(b) (<i>(6)</i>			
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WORK PHONE	WORK PHONE			
RESPONSIBLE PARTY INFORMATION NAME (Last, First Middle)	ON (if Different than above)	SSN# BIRT	HDATE LANGUAGE	SEX
LOCAL ADDRESS	SECONDARY/BILLING	ADDRESS (if Applicable)		1
CITY, STATE ZIP	CITY, STATE ZIP			
HOME PHONE	HOME PHONE			
RELATIONSHIP TO PATIENT				
PRIMARY INSURANCE		POLICY#		
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SECONDARY INSURANCE (IT Applic NAME OF INSURANCE COMPANY		POLICY#		
SECONDARY INSURANCE (IF Applic NAME OF INSURANCE COMPANY NAME OF INSURED				
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RELATIONSHIP TO PATIENT PRIMARY INSURANCE (b) (4) NAME OF INSURANCE COMPANY NAME OF INSURANCE COMPANY ADDRESS OF INSURANCE COMPANY CITY, STATE ZIP DEDUCTIBLE	CITY, STATE ZIP	CITY, STATE ZIP			<u> </u>	
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(if Applicable) NAME OF INSURANCE COMPANY NAME OF INSURED ADDRESS OF INSURANCE COMPANY CITY, STATE ZIP GEDUCTIBLE	RELATIONSHIP TO PATIENT					
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CITY, STATE ZIP DEDUCTIBLE	NAME OF INSURED		GR	OUP#		
	ADDRESS OF INSURANCE COMPANY		co	PAY AMT		
RELATIONSHIP TO PATIENT EXPIRATION DATE EXPIRATION DATE	CITY, STATE ZIP		ΩE	DUĆTIBLE		
	RELATIONSHIP TO PATIENT		EFI	ECTIVE DATE	EXPIRATION DAT	E

These are the procedures as stated to us by (b) (6)

(b) (6) applied 2 drugs (undecipherable) to the eye. He then applied one drop of butadiene to the eye. He then removed the sterile lid speculum and injected Avastin. He applied a drop of antibacterial medicine, and replaced the sterile lid. (b) (6) followed up with patients. He administered Vancomycin and Amikacin. He conducted a vitrious tap and anterior chamber tap, which are typical procedures. The taps came back positive for growth. He administered more vancomycin and triamcinolone intraventricularly. He conducted a vitrectomy and a vitrious biopsy, and administered more vancomycin. For the second affected patient, the vitrectomy was conducted, and the patient was administered triamcinolone.

Attachment _11_ Total pgs _1_ Page 1

label outside outer envelope only

KEEPINDEFRIGERATOR DONOT FREEZE

CHRONISCRIPT, A WALGREENS PHARMACY
1250 NW 7TH STREET SUITE 205 MAMM. FL 33125131035547-4790 - Fax (305)547-4796 TOLL FREE 866-469-6337
1310355547-4790 - Fax (305)547-4796 TOLL FREE 866-469-6337

Rxf:130450

06/29/2011

Phar DEAmFW2370524

INTRAVITREAL INJECTION INTO THE LEFT EYE (DOSE TO BE ADMINISTERED IS 1.25 MG/0.05 ML) DISCARD REMAINDER

AVASTIN 2.5 MG/0.1 ML PFS SYR

This Pharmacy

BEVACIZUMAB
ORIG RX DATE: 06/23/2011 3 REFILLS BEFORE 06/22/2012

00000-0000-00 Use Before 07/13/2011

May cause dizziness

Keep in retrigerator. Do not

CHRONISCRIPT, A WALGREENS PHARMACY

CHRONISCRIPT, A WALLEREENS PERRMACY 1250 NW 7TH STREET SLITE 206, 98AMIL PL 23125 TOLL FREE 366-469-5387 THI 13081447-4790 - Fax (305)547-4796

06/24/2011 RX#:130441

INTRAVITREAL INJECTION INTO THE RIGHT EYE

(DOSE TO BE ADMINISTERED IS 1.25 MG/0.05 ML) DISCARD REMAINDER

GNT: 1.0 EACH 6 REFULS BEFORE 06/22/2012 BEVACIZUMAB

ORIG RX DATE: 06/23/2011 00000-0000-00 Use Before 07/08/2011

> AVASTIN 2.5MG/0.1ML XT: 07012011 EXP: 8/01/11

s6d Walgreens Co. El: 07/20/11 - 08/16/11 Attachment _12_ Total p

(b) (4) patient summary

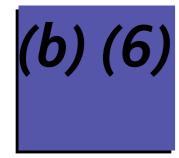
PATIENTS ON CHRONISCRIPT LIST LOT#/RX# IJECTION DA'DRUG RECEIVEL

ADDITIONAL COMMENTS

<i>(b)</i>	(4)

131303 7/8/2011	7/6/2011 Patient dx with infection & treated on 7/11/11 se	nt to <u>(6) (4)</u> on 7/13/11
57619 7/11/2011	6/29/2011 Patient examined 7/12/11 thru 7/13/11 No infe	ction
07012011 No inj given	7/5/2011 Prefilled syringe sent to (b) (4)	7/12/11
130450 No inj given	7/5/2011 Prefilled syringe sent to (b) (4)	7/12/11
6/17/2011	6/14/2011 Patient examined 7/15/11 No infection	
06082011 6/22/2011	6/15/2011 Patient phone disconnected	., කූ ජ
06082011 6/30/2011	6/15/2011 Patient examined 7/18/11 No infection	96723358 WM, CAG

(b) (4) PATIENTS FROM 6/1/11 TO 7/18/11



57442	7/1/2011	6/27/2011 Patient examined 7/14/11 No infection
57547	7/5/2011	6/28/2011 Patient examined 7/14/11 No infection
57447	7/5/2011	6/28/2011 Patient examined 7/15/11 No infection
57624	7/11/2011	6/29/2011 Patient examined 7/12/11 & 7/14/11 No infection

FAX:

AUG-08-2011 09:10

SAMPLES (Avastin)	Culture Results/Organisms	Source	Lot Number	
	1 positive/Streptococcus mitis/oralis	Avastin	7062011	
	2 positive/Streptococcus mitis/oralis	Avastin	7062011	
·	3 positive/Streptococcus mitis/oralis	Avastin	7062011	
	4 No growth	Avastín	6222011	
	5 positive/Streptococcus mitis/oralis	Avastin	7012011	

(b) (4), (b) (5), (b) (7)(A)