

Memorandum



Subject

Internet Presentation with Anda Inc. on September 9, 2005
(DFN: 060-06.05)

Date

OCT 20 2005

To

Joseph Rannazzisi
Acting Deputy Assistant Administrator
Office of Diversion Control

From

Michael R. Mapes
Michael R. Mapes, Chief
E-Commerce Section (ODC)

On September 9, 2005, a meeting was held at the Office of Diversion Control conference room. In attendance were Mr. Michael Cochrane, Regulatory Compliance Manager, Herschel E. Sparks Jr., Litigation Counsel for Anda Inc., Michael R. Mapes, Chief, E-Commerce Section, Charles E. Trant, Office of Chief Counsel, Diversion & Regulatory Litigation Division, and Kyle J. Wright, Chief, E-Commerce Operations Unit. The purpose of the meeting was to address the illegal domestic Internet pharmacy problem and their source of supply.

Mr. Mapes opened the meeting by presenting to Mr. Cochrane and Mr. Sparks a power point briefing which explained the common characteristics of Internet pharmacies and why their activities are illegal. Reviewed with the representatives of Anda Inc. were:

- Supreme Court Cases and Immediate Suspension orders of Internet pharmacies.
- Establishing the medical need necessity for a prescription to be legal.
- The DEA Internet Policy.
- Verified Internet Pharmacy Practice Sites (VIPPS).
- Policies published by the American Medical Association (AMA) and the Federation of State Medical Boards.
- Review of the suspicious order requirements Title 21, Code of Federal Regulations.
- Common practices and ordering patterns of Internet pharmacies.
- Examples of two Internet pharmacies highlighting the brazenness of activity to which Internet pharmacies will go to.

After the presentation, Mr. Mapes presented to Mr. Cochrane and Mr. Sparks specific customers of Anda Inc., which have raised significant concerns with the DEA from the substantial quantities of hydrocodone products being ordered. The specific customers of Anda Inc. were:

[REDACTED]

PLAINTIFFS TRIAL
EXHIBIT
P-09113_0001

Mr. Mapes finalized the presentation by advising the representatives of Anda Inc. that they needed to thoroughly review the materials which had been presented to them and review in-depth the purchasing patterns and quantities of their customers. Mr. Mapes further informed Anda Inc. they were the primary supplier to virtually every identified Internet Pharmacy.

Mr. Cochrane and Mr. Sparks both acknowledged understanding of the material presented and the seriousness of their responsibilities and assisting in addressing the issues presented.

In consultation with Mr. Trant, it was agreed, that if E-Commerce Operations (ODCO) were to identify a highly suspicious pharmacy to which Anda Inc. was the wholesaler, ODCO would notify Anda Inc. via e-mail of the suspicious activity for Anda Inc. to review and take the actions the company deems appropriate. Mr. Mapes also informed the representatives of Anda Inc., if he desired further information, or training, to notify ODCO which would provide the requested information or training.



The meeting between Anda Inc. and DEA was ended at this time, with each party having a clearer understanding and agreement as to how best address the sources of supply to Internet pharmacies.

Attachments:

1. Briefing Binder
2. Charts of Anda's Customers

CC: DPM Barbara McGrath
Miami Field Division

bcc: ✓DFN: 060-06.05
Chron

ODC 
ODCO :KWright:pln:703-653-2103:10/21/05
Filename: Anda.doc

INTERNET PHARMACY DATA

Meeting With
Anda Inc.
DEA Headquarters
September 9, 2005

Internet Pharmacies

- Domestic Based
 - Related to an existing pharmacy
 - Walk in patients with prescriptions
 - Some legitimate some not
 - Unrelated to brick and mortar pharmacy
 - No local patients or doctors
 - No walk-in business
- Foreign based

Involved With Internet Pharmacies

- Doctors
- Pharmacies
- Distributors

- Internet Service Providers
- Credit Card Companies
- Delivery Services
- Internet Pharmacy Facilitators

ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor

DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
 - Is the registration in the public interest?
 - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
 - Mail order sales to doctor
 - Most sales were Morphine
 - Increase in quantities purchased
 - Business practices attracted customers who were violating the law
 - Drugs have inherent susceptibility to harmful and illegal use

EZ RX, LLC

- 69 FR 63,178 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 300,000 dosage units in three months
 - Phentermine, Phendimetrazine, Ambien

RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 19,300,000 dosage units of various controlled substances
 - Based on Internet Questionnaires
 - Not in the course of professional practice

Supreme Court Case

- United States v. Moore
423 U.S. 122 (1975)
 - Usual course of professional practice
 - Patient with a Medical Complaint
 - History
 - Physical Examination
 - Nexus Between Complaint/History/Exam and Drug Prescribed

DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

VIPPS

- National Association of Boards of Pharmacy
 - Licensed, legitimate, Inspection
 - Verified Internet Pharmacy Practice Sites
 - 14 VIPPS Approved Pharmacies as of 06-27-2005
 - www.nabp.net/vipps/consumer/faq.asp

American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
 - valid patient-physician relationship, includes, but not limited to:
 - History and physical exam
 - Dialogue with patient
 - Follow up to assess outcome
 - Maintain medical record
 - Include electronic prescription in patient's medical record

Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
 - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
 - Treatment based solely on an online questionnaire is not acceptable

Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate system to identify suspicious orders
- Report suspicious orders to DEA when discovered

Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

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SINGLE CASE

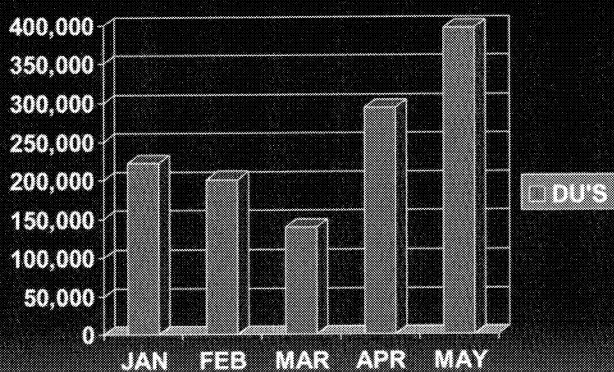
Suspicious Orders

- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision

Example #1

- Retail pharmacy
 - Quantities of drugs
 - Range of drugs sold – only Phentermine
 - % controlled and % non-controlled
 - Size of orders over time
 - Location of store

Example #1

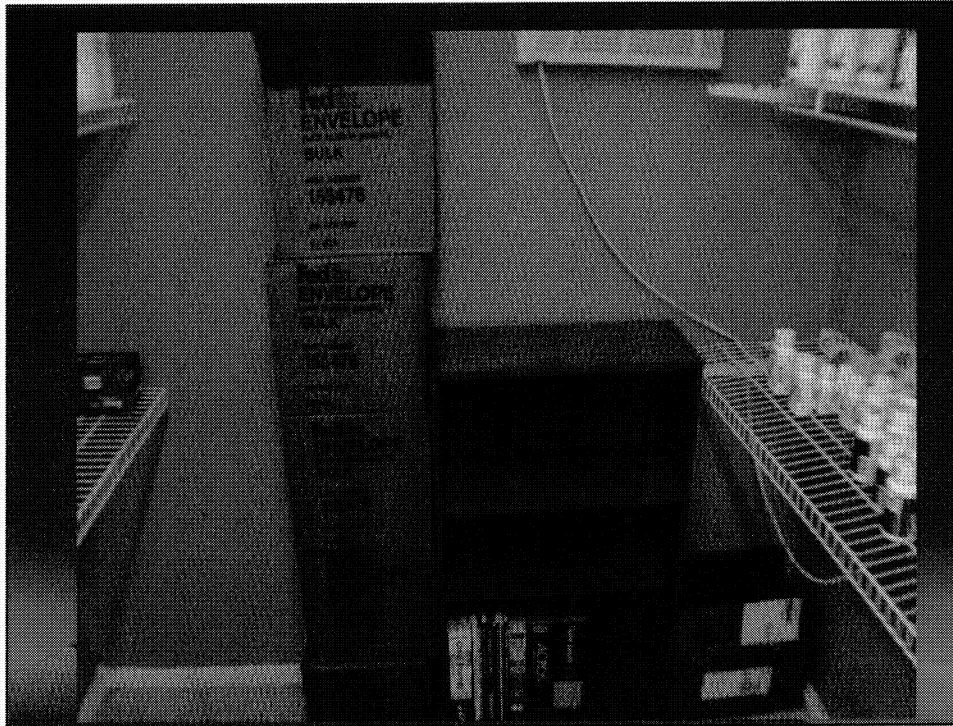


Example #2

- Retail Pharmacy
 - Location of store
 - Only Hydrocodone and Alprazolam
 - Very large quantities
 - FedEx boxes for delivery

ANOTHER PHARMACY





Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

AN INTERNET PHARMACY



SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharmacies

SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

SUMMARY

- DEA will:
 - Meet with other distributors involved in distributing to Internet pharmacies
 - Provide this information to your employees at your request
 - Meet with Industry groups or associations to discuss issue if requested

Contact Information

Michael Mapes

Chief, E-Commerce Section

703-653-2048

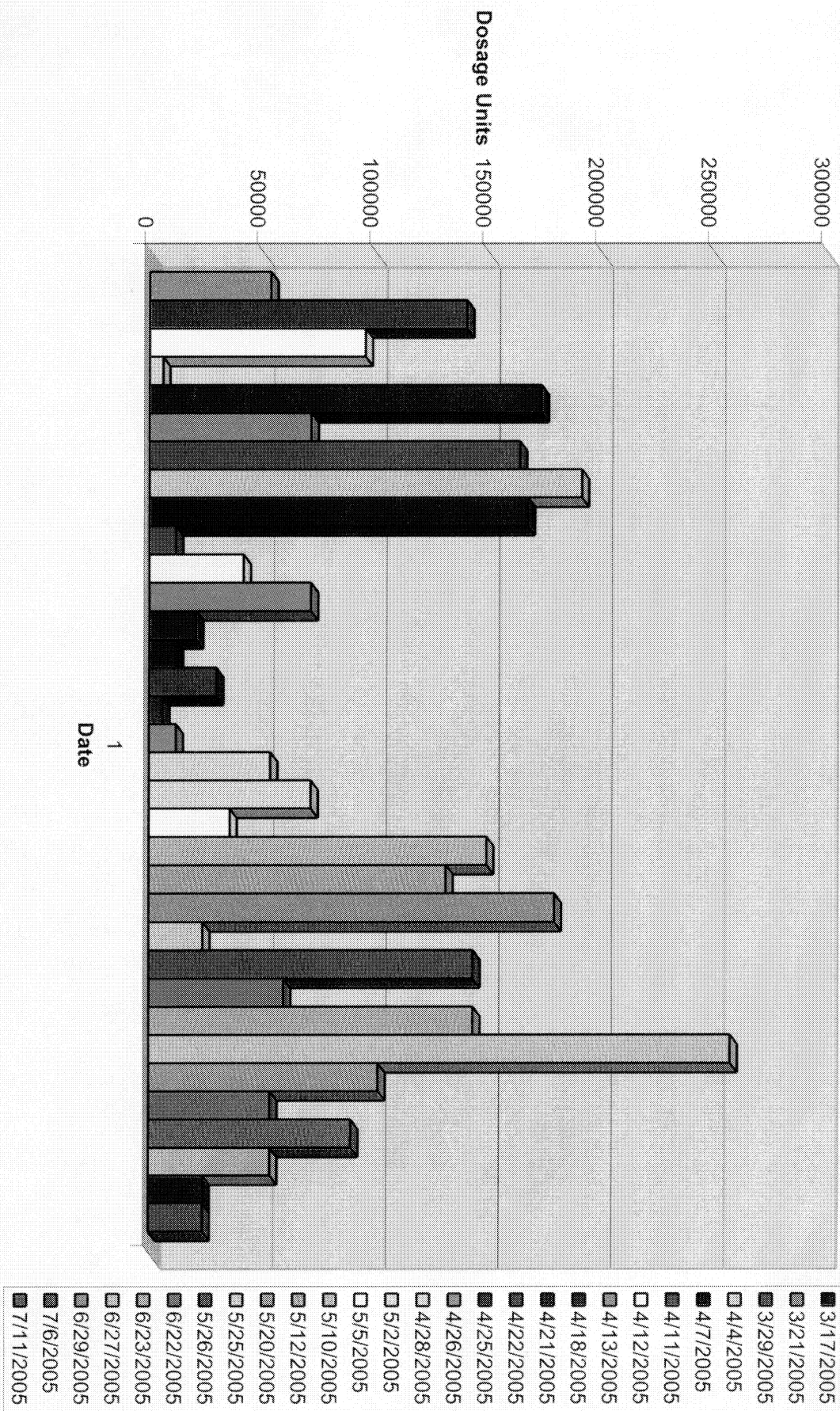
Kyle Wright

Chief, E-Commerce Operations Unit

703-653-2103

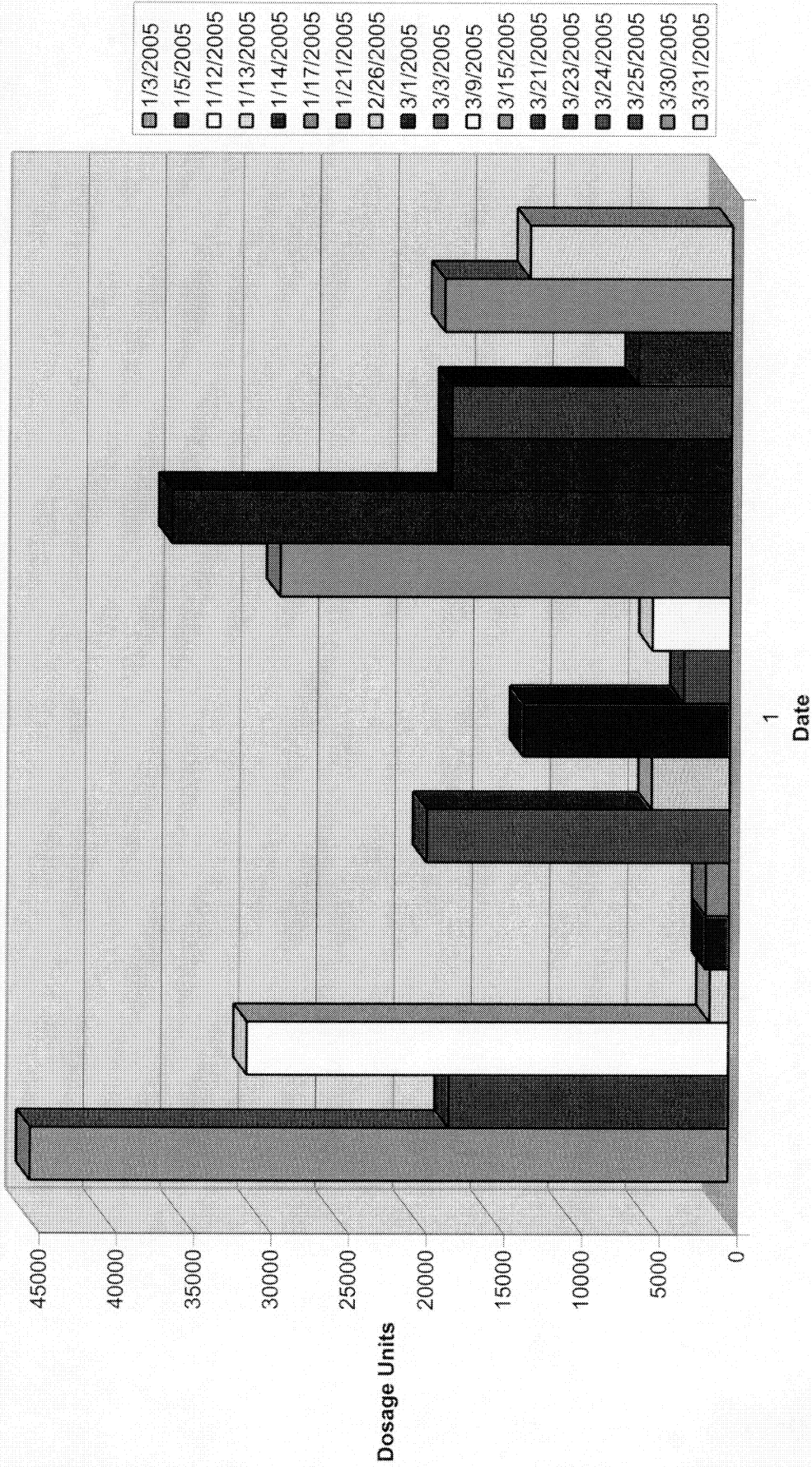
Anda's Hydrocodone sales to Direct Dispensing

A MANUFACTURER - NO ARCOS REPORTS



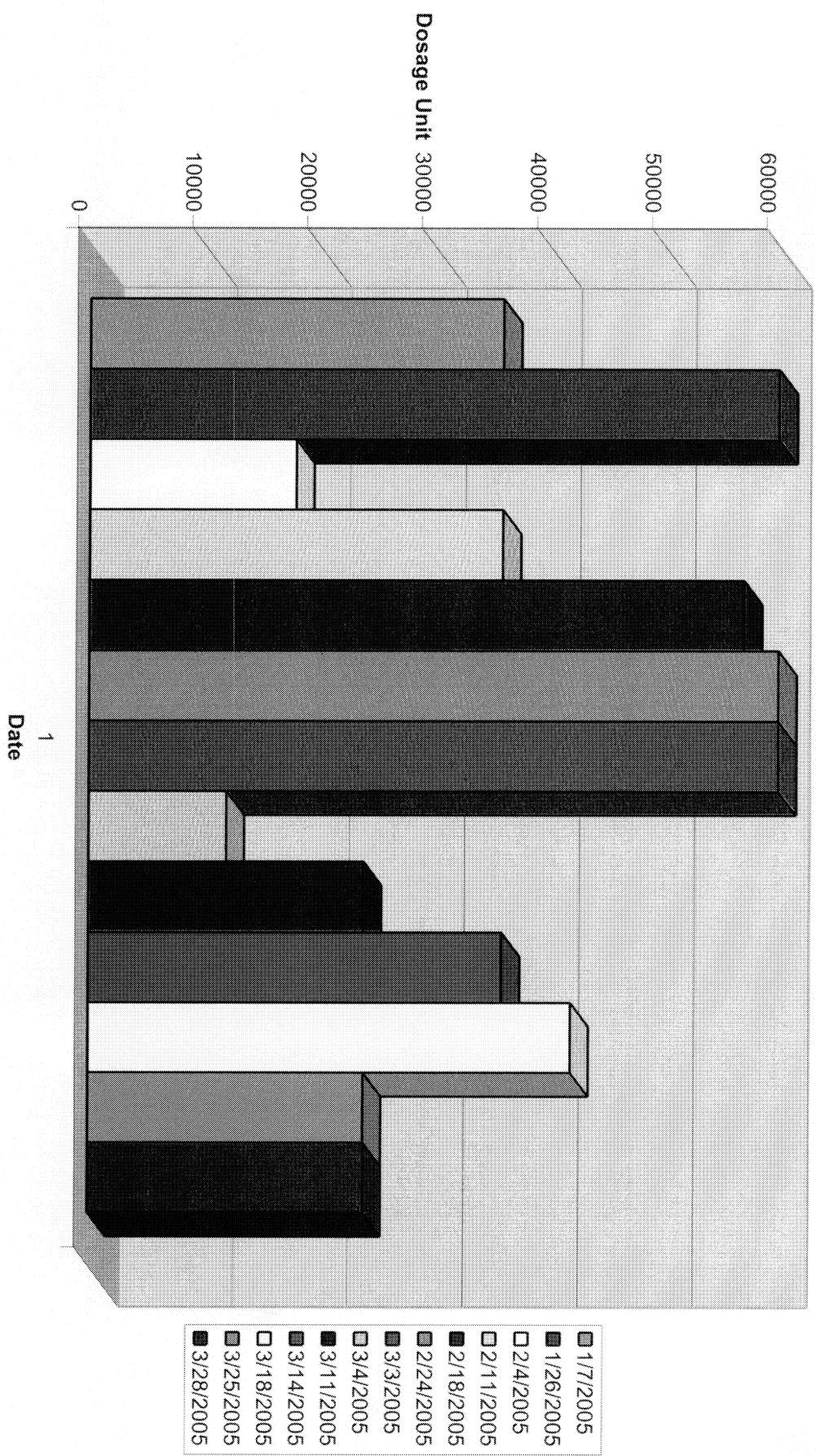
Direct Dispensing purchased 2,888,500 dosage units of Hydrocodone from ANDA from 1-24-05 through 6-29-05. There are no ARCOS sales records from Direct Dispensing

Anda's Hydrocodone sales to Hollywood Pharmacy



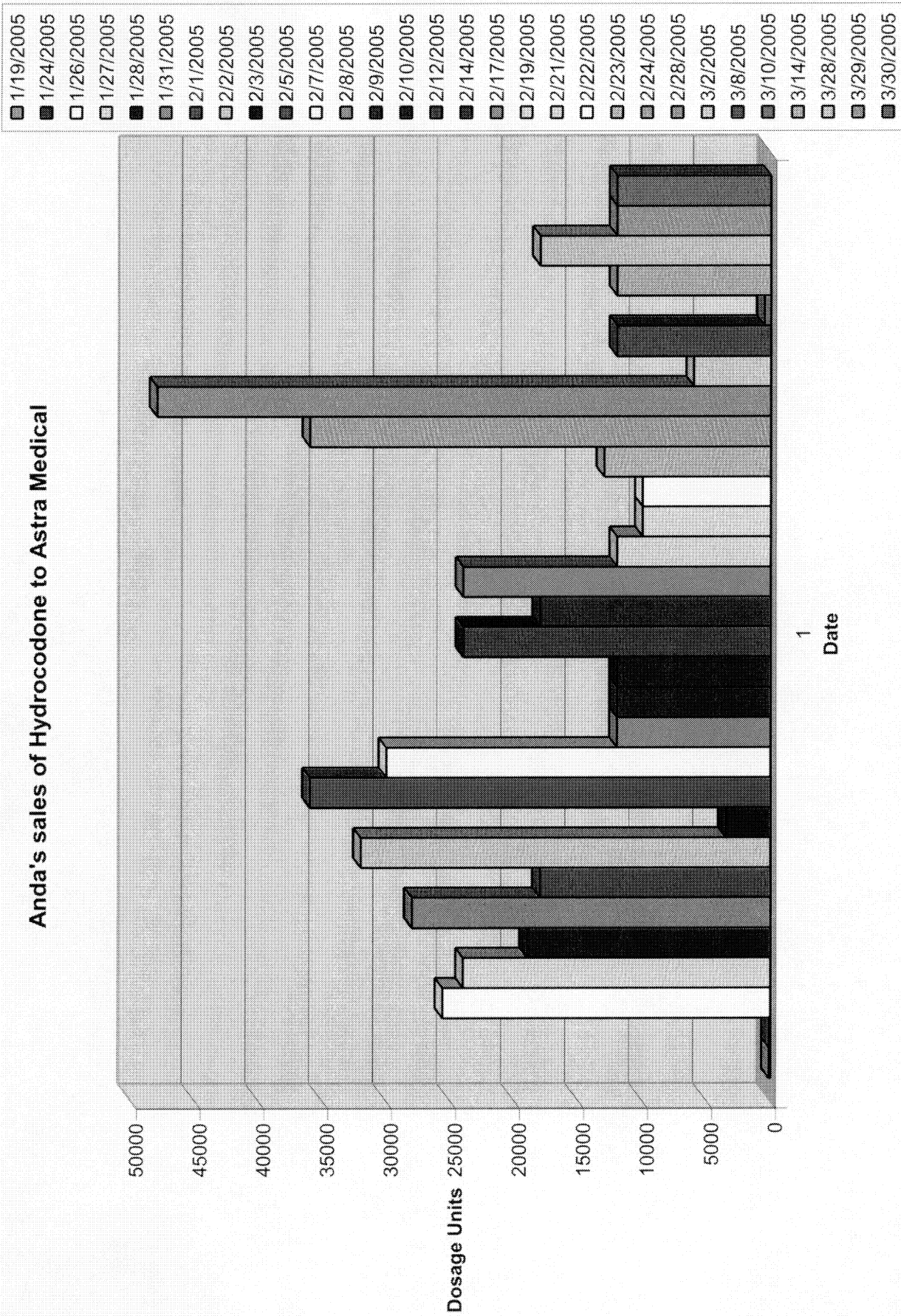
Total sales from 1-3-05 through 3-31-05 equals 282,000 dosage units

Anda's Hydrocodone sales to Prescription RX



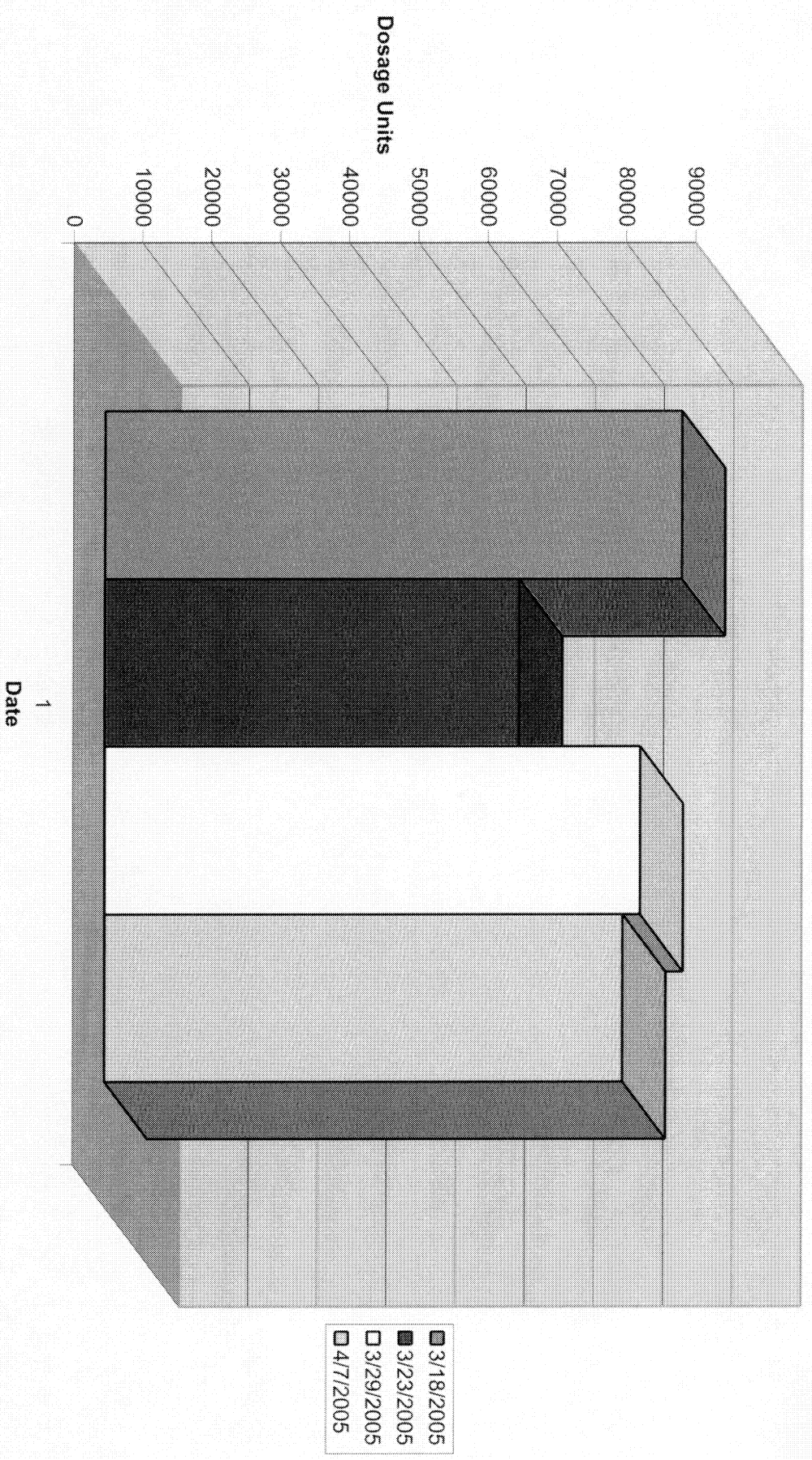
Total sales from 1/7/05 through 3/28-05 equals 489,000 dosages units

Anda's sales of Hydrocodone to Astra Medical



Total sales from 2-1-05 through 3-30-05 equals 519,800 Dosage Units

Anda's sales of Hydrocodone to Barbie's Pharmacy



Total sales from 3-18-05 through 4-7-05 equals 296,000 Dosage Units

Memorandum



Subject

Distributor Initiative Meeting with Watson Pharmaceuticals Inc., and Anda Inc., on August 23, 2007.
(DFN: 060-06.05)

Date

SEP 18 2007

To

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

From

Michael R. Mapes
Michael R. Mapes, Chief
Regulatory Section (ODG)
Office of Diversion Control

On August 23, 2007, a meeting was held at the Office of Diversion Control conference room between the DEA, Watson Pharmaceuticals and their subsidiary Anda, Inc. Representing Watson and Anda were the following individuals; Tracey Hernandez, Director, Corp. Controlled Substance Compliance, Watson Laboratories; Diane Miranda, Vice President, Watson Pharma, Inc.; Albert Paonessa, COO, Anda Inc.; and Michael Cochrane, Director Regulatory compliance, Anda Inc. Representing the DEA Office of Diversion Control were the following individuals; Michael R. Mapes, Chief, Regulatory Section; Kyle J. Wright, Staff Coordinator, Operations Section; Lisa D. Sullivan, Staff Coordinator, Operations Section; Barbara McGrath, Diversion Program Manager, Miami Division; Dawn Valerie Mitchell, Diversion Investigator, Columbus, Ohio. The purpose of the meeting was to address the questionable distribution practices of controlled substances by Anda Inc. Anda Inc., has facilities in Weston, Florida and Groveport, Ohio.

Mr. Mapes opened the meeting by presenting to representatives of Watson Inc., and Anda Inc., a power point presentation that explained the common characteristics of Internet pharmacies and why their activities are illegal. This presentation had previously been presented to representatives of Anda Inc., on September 10, 2005. Watson recently acquired Anda Inc., and as such now shares management responsibility in decisions that Anda Inc., makes. Specifically reviewed were the following:

- Supreme Court Cases and Immediate Suspension orders of Internet pharmacies.
- Establishing the medical need necessity for a prescription to be legal.
- The DEA Internet Policy.
- Verified Internet Pharmacy Practice Sites (VIPPS).
- Policies published by the American Medical Association (AMA) and the Federation of State Medical Boards (FSMB).
- Review of the suspicious order requirements Title 21, Code of Federal Regulations.
- Common practices and ordering patterns of Internet pharmacies.
- Examples of two Internet pharmacies highlighting the activity of Internet pharmacies.
- Recent action by the DEA to suspend or revoke controlled substances licenses of distributors and pharmacy that continue to divert controlled substances to the illegal markets.

After the presentation, Mr. Mapes presented six charts of current Anda Inc., customers which had suspicious ordering patterns or quantities. Mr. Paonessa stated that as of mid July 2007, Anda Inc., had rewritten the program used in their warehouse management system to identify all orders of controlled substances by chemical or family name i.e. hydrocodone as opposed to Stock Keeping Unit (SKU) numbers i.e. Watson brand Vicodin. Previously Anda Inc., was tracking orders by SKU numbers and as a result was not able to identify when their customers were ordering large quantities of products from the same chemical family. Anda Inc., has also begun tracking by customer DEA registration number so that their customers will not be able to exceed set dosage units limits by purchasing from both locations.

Mr. Mapes explained to the representatives of Watson and Anda the suspicious order reporting requirements that are addressed in the Code of Federal Regulations. Mr. Mapes requested that Anda Inc., voluntarily submit on a daily basis all controlled substances distributed using an ARCOS string submission to the DEA. Additionally, it was requested that suspicious orders be reported in the same manner. Mr. Paonessa believed that the daily transactions could be done in a reasonable amount of time however the suspicious order submissions would require some program review and would take longer.

The representatives for Watson Inc., and Anda Inc., were informed that while they appear to have taken measures to prevent the illegal distribution of controlled substances they were still accountable for previous distribution activities. The meeting between Watson Pharmaceuticals, Inc., Anda Inc., and DEA was ended at this time.

Attachments:

1. Briefing Binder
2. Charts of Anda Inc. Customers

cc: Denise Curry, OD/D
DPM Barbara McGrath, Miami Division
DPM James Geldolf, Detroit Division

Effective Controls Against
Diversion of Controlled
Substances
Meeting with
Watson Pharmaceuticals
August 23, 2007

(M)

Effective Controls Against Diversion of Controlled Substances

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CRJ Pharmacy, Inc., & YPM Total Care Pharmacy, Inc.

- 72 FR 30,846 (2007)
 - Immediate Suspension Order
 - Revocation of Registration
 - Between Jan – Nov 2006, CRJ dispensed 1,416,320 d.u. of hydrocodone products.
 - Between May – Nov 2006, YPM dispensed 846,800 d.u. of hydrocodone products.
 - Prescriptions were filled based upon an on-line questionnaire.

Southwood Pharmaceuticals, Inc.

- 72 FR 36,487 (2007)
 - Revocation of Registration
 - Immediate Suspension Order
 - Failure to maintain effective controls against diversion
 - Supplied millions of dosage units of controlled substances to Internet pharmacies
 - Failure to exercise due diligence (21 USC 823)

Supreme Court Case

- **United States v. Moore**
423 U.S. 122 (1975)
 - Usual course of professional practice
 - Patient with a Medical Complaint
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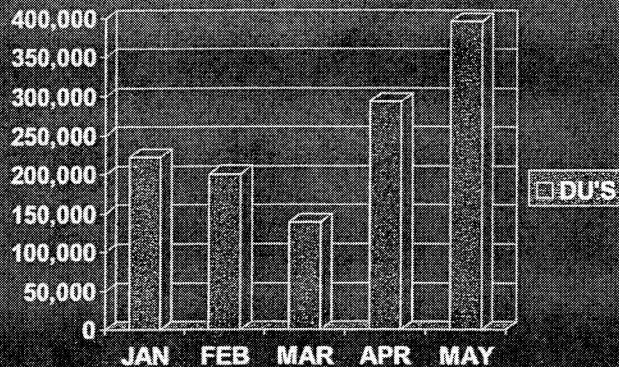
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Example #2

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 - Very large quantities
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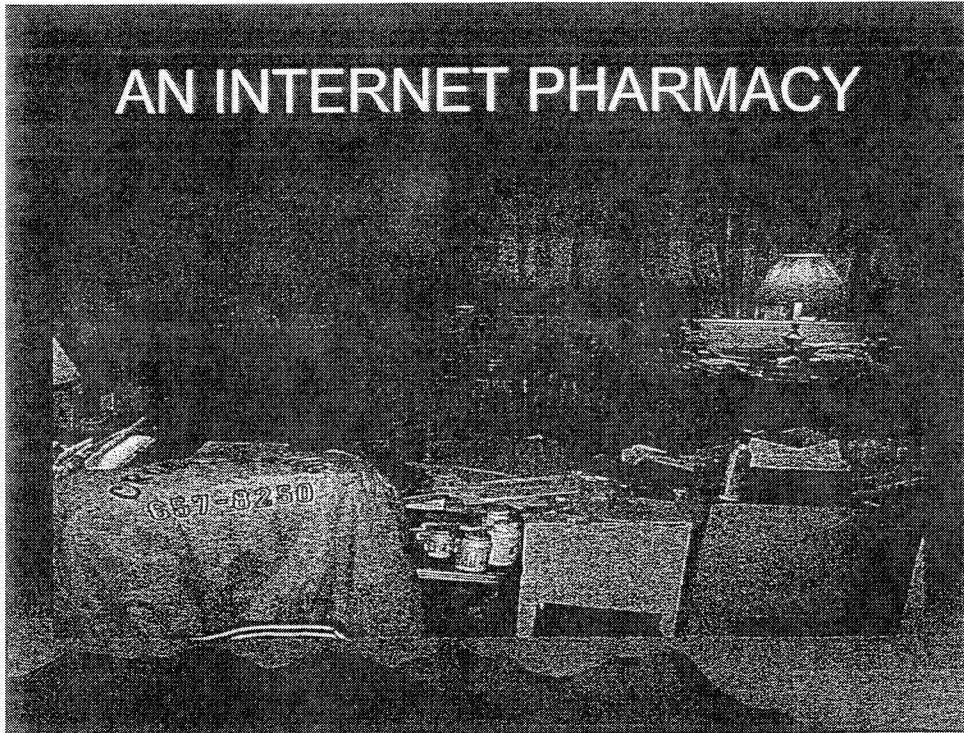
ANOTHER PHARMACY



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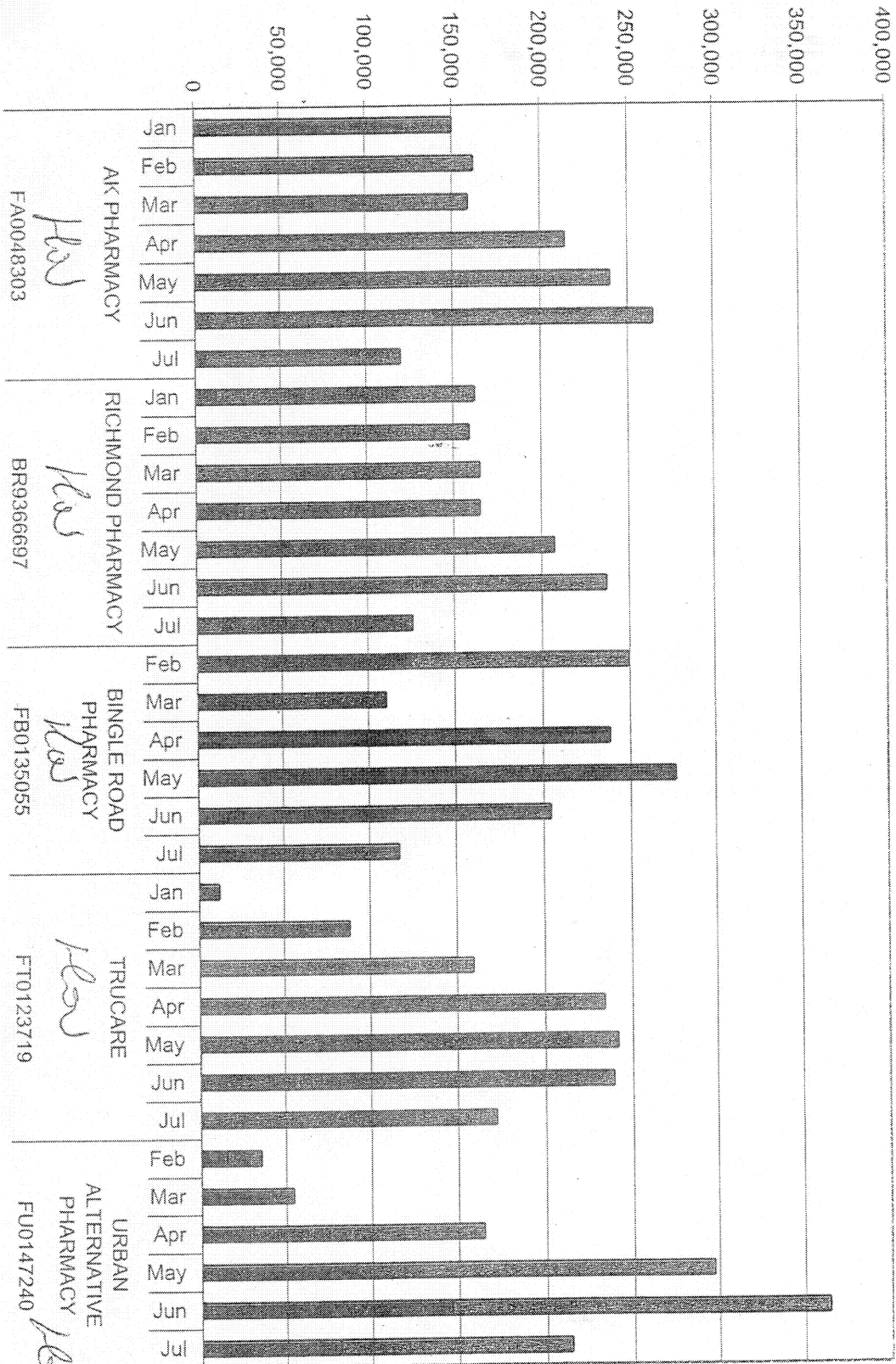
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Contact Information

Matthew Murphy, Chief
Pharmaceutical Investigations Section
202-307-8008

Kyle Wright, Staff Coordinator
Pharmaceutical Investigations Section
202-658-7514

ANDA Ohio and Florida hydrocodone (dosage units) sales to the combined top 5 pharmacies
January-July, 2007

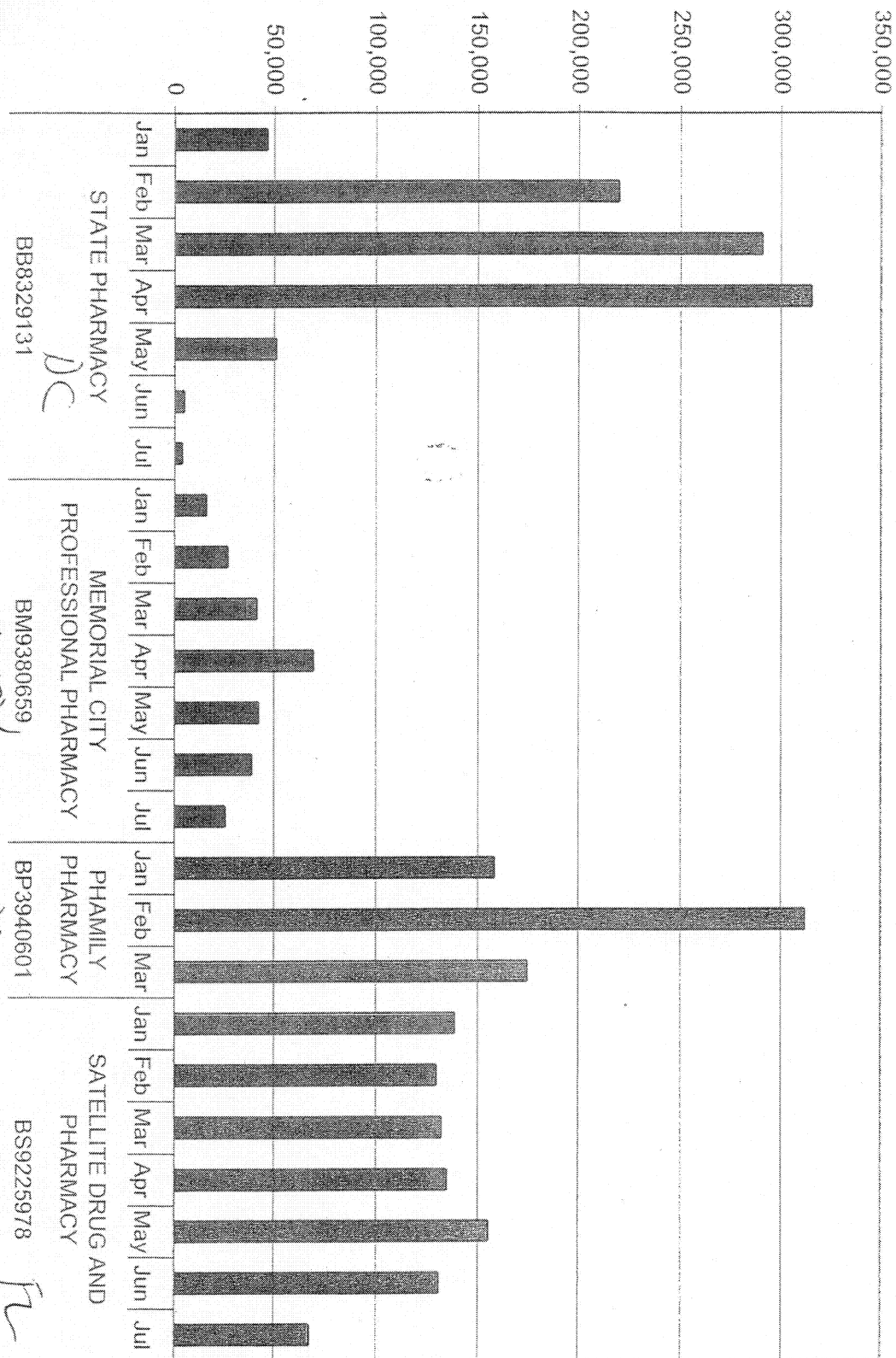


RA0287020
 RA0180733

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MO - CM

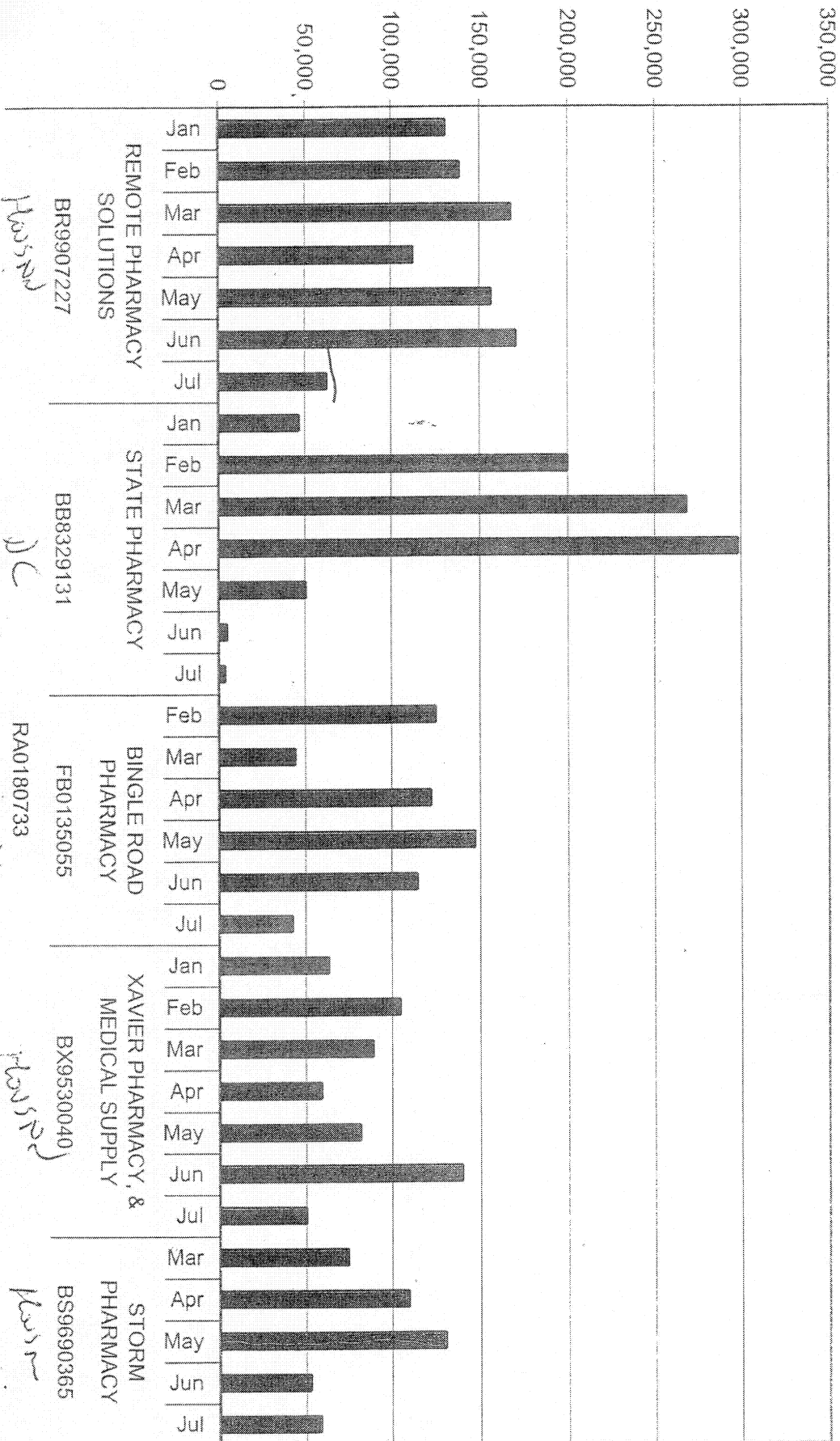
ANDA Ohio and Florida hydrocodone sales (dosage units) to the top known internet pharmacies
 January 2007-July 2007



RA0287020
 RA0180733
 -DM
 -FL

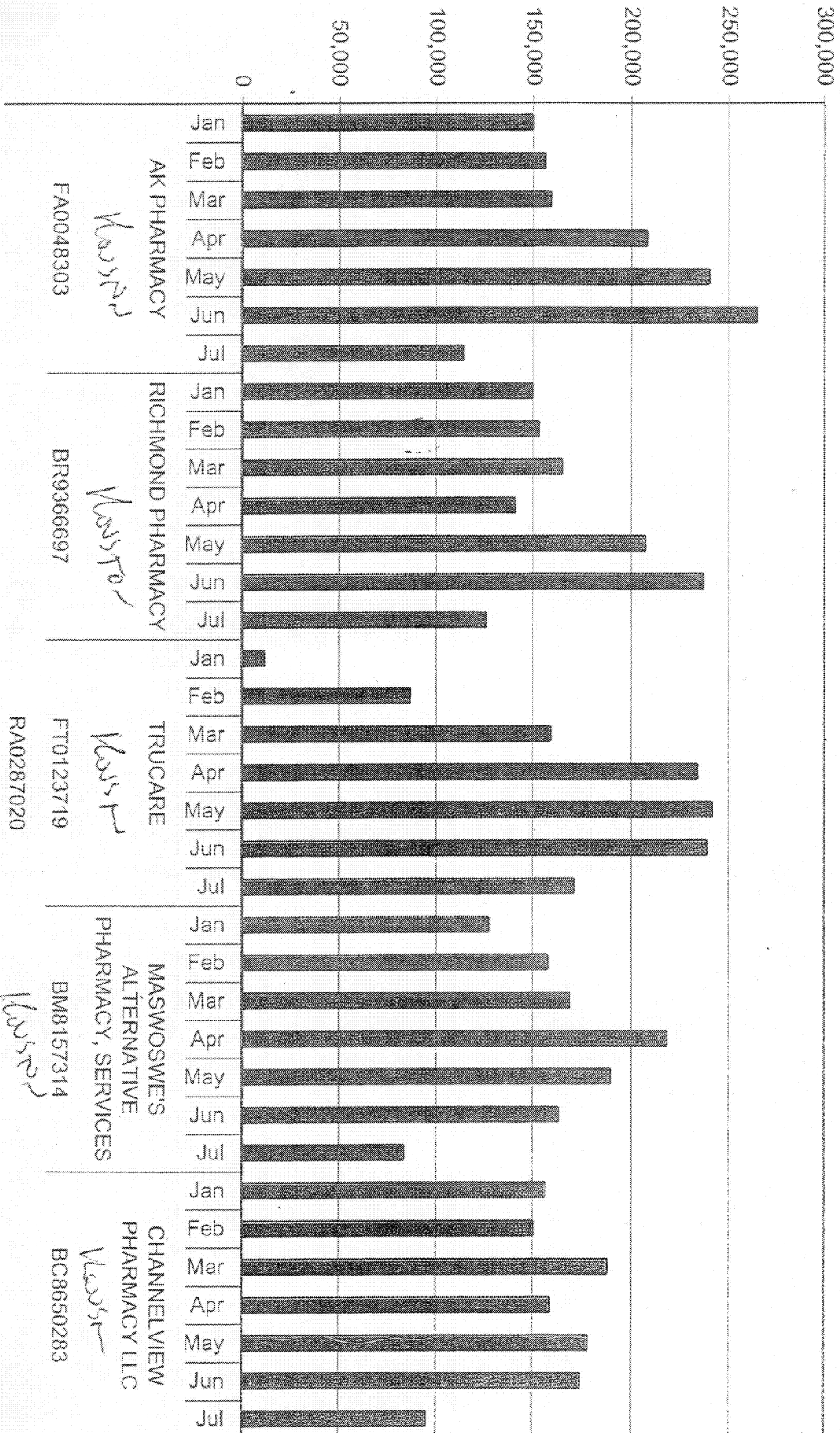
Hydrocodone sales (dosage units) to the top 5 pharmacies
by ANDA RA0180733 January - July 2007

FL

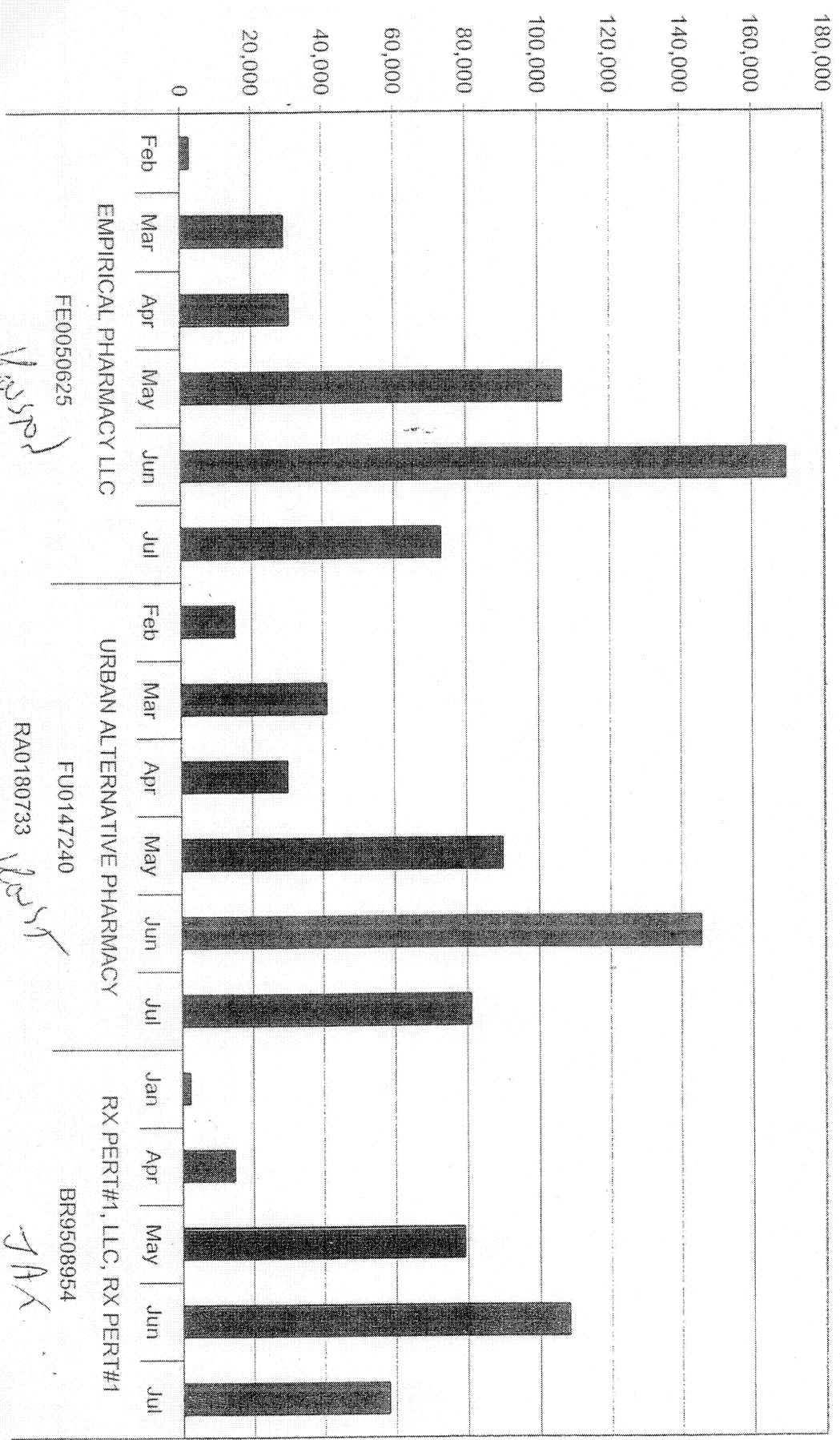


Hydrocodone sales (dosage units) to the top 5 pharmacies
by ANDA RA0287020 January - July 2007

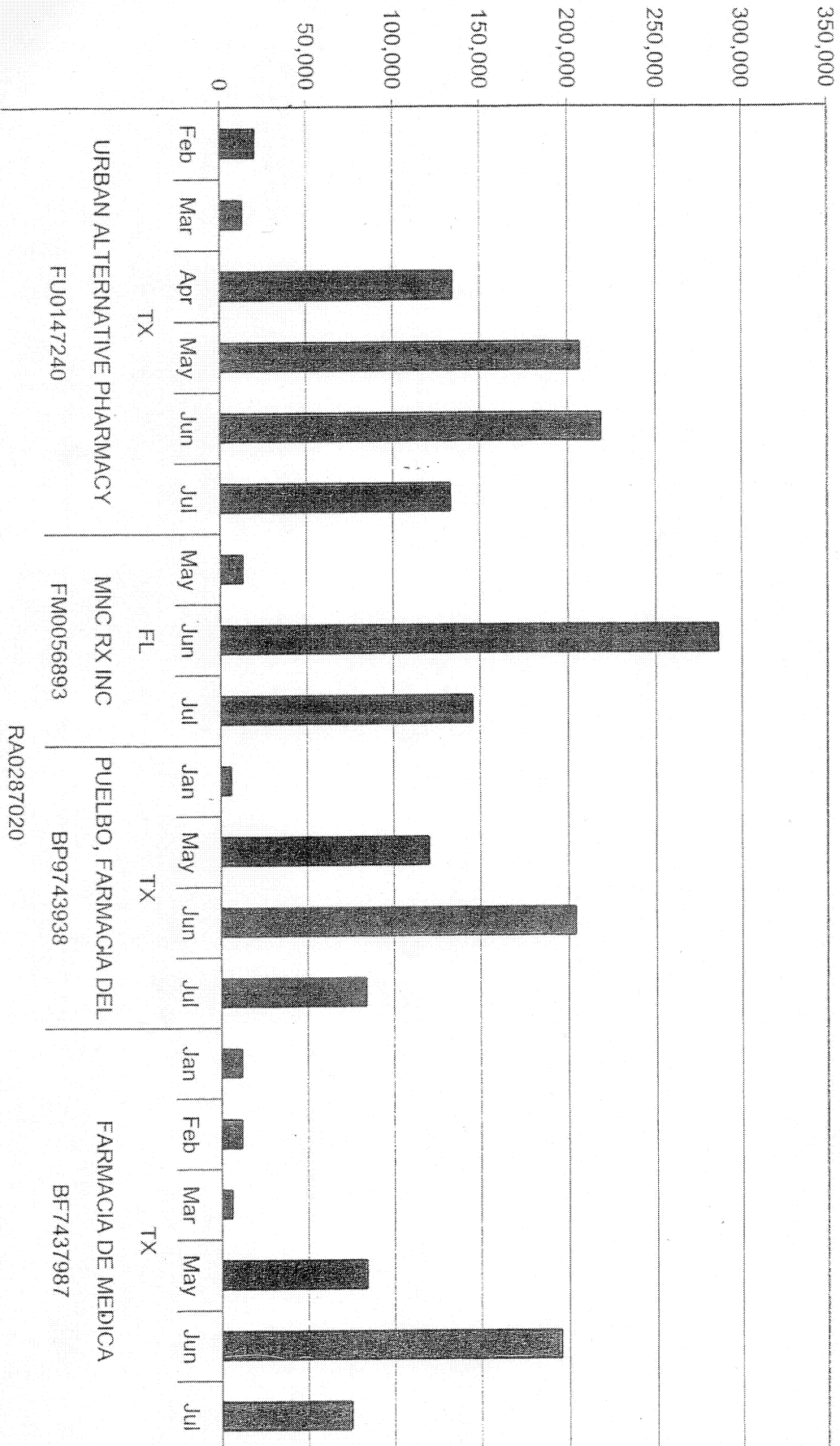
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Examples of spikes in hydrocodone (dosage units) sales to pharmacies
 by ANDA RA0180733 January-July 2007



Examples of spikes in hydrocodone (dosage units) sales to pharmacies
by ANDA RA0287020 January -July 2007



ANDA Ohio and Florida hydrocodone sales to pharmacies January-July 2007

DEA #	dosage units purchased at pharmacies	number of pharmacies	
RA0180733	>1,000,000	0	0.0%
RA0180733	800,000-999,999	2	0.1%
RA0180733	500,000-799,000	2	0.1%
RA0180733	100,000-499,000	55	1.7%
RA0180733	50,000-99,000	88	2.7%
RA0180733	10,000-49,000	483	14.8%
RA0180733	<10,000	2,641	80.7%
RA0180733	Total	3,271	
RA0287020	>1,000,000	5	0.1%
RA0287020	800,000-999,999	2	0.0%
RA0287020	500,000-799,000	10	0.2%
RA0287020	100,000-499,000	70	1.7%
RA0287020	50,000-99,000	148	3.6%
RA0287020	10,000-49,000	797	19.5%
RA0287020	<10,000	3,058	74.8%
RA0287020	Total	4,090	