

**BEFORE THE IOWA BOARD OF PHARMACY**

Re: )  
Wholesale Drug License of ) Case No. 2009-48  
**NATIONAL PHARMACEUTICAL** )  
**RETURN** ) **STATEMENT OF CHARGES**  
License No. 5261, )  
Respondent. )

**COMES NOW**, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2009).
3. Effective November 10, 2008, the Board renewed Respondent's wholesale drug license number 5261, allowing Respondent to engage in the operation of a reverse distributor pursuant to the laws of the State of Iowa and the rules of the Board.
4. Wholesale drug license number 5261 is current through December 31, 2009.
5. Respondent is currently operating a reverse distribution center at 4164 Northwest Urbandale Drive, Des Moines, Iowa 50322.

**A. CHARGES**

**COUNT I – LACK OF PROFESSIONAL COMPETENCY**

Respondent is charged pursuant to Iowa Code § 155A.17 (2007) and 657 Iowa Administrative Code §§ 17.18 and 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa.

## COUNT II – FAILURE TO MAINTAIN SECURITY SYSTEM

Respondent is charged pursuant to Iowa Code § 155A.17 (2009), and 657 Iowa Administrative Code §§ 17.10(3) and 17.18, with failing to maintain an adequate security system to prevent theft and diversion of drugs, including controlled substances.

## COUNT III – FAILURE TO MAINTAIN ADEQUATE RECORDS

Respondent is charged pursuant to Iowa Code §§ 124.306, 124.402(1), 155A.17 (2009), and 657 Iowa Administrative Code §§ 17.16, 17.16(1) 17.16(2), 17.16(3), 17.18 and 36.1(4)(ac), with failing to maintain complete, accurate and accessible records of drug transactions, including transactions involving controlled substances.

## COUNT VI – SUBVERTING BOARD INVESTIGATION

Respondent is charged pursuant to Iowa Code § 155A.17 (2009), and 657 Iowa Administrative Code §§ 17.18 and 36.1(4)(z), with subverting a Board investigation by maintaining multiple, irreconcilable controlled substance inventories, by 'whiting out' DEA Form 222 documents, by failing to maintain paper records to support computer entries, and by generally failing to maintain accurate drug transaction records, including transactions involving controlled substances, such that an accurate audit of Respondent's operation is rendered impossible.

## COUNT V – FAILURE TO NOTIFY BOARD OF LOSSES

Respondent is charged pursuant to Iowa Code §§ 155A.17 and 155A.19(3)(f) (2009), and 657 Iowa Administrative Code §§ 17.18 and 36.1(4)(j), with failing to notify the Board upon discovery of losses of controlled substances.

## COUNT VI – VIOLATION OF FEDERAL LAWS

Respondent is charged pursuant to Iowa Code § 155A.17(2) (2009), and 657 Iowa Administrative Code §§ 17.17, 17.18 and 36.1(4)(j), with violating the laws of the United States by improperly storing controlled substances (a violation of 21 CFR §§ 1301.71(a) and 1301.72(a)), by failing to maintain complete and accurate records of controlled substance transactions (a violation of 21 CFR §§ 1304.21(a) and 1304.22(e)), by failing to maintain complete, accurate, and unaltered DEA Forms 222 (a violation of 21 CFR § 1305.13(e)), and by improperly creating DEA Forms 41 regarding destruction of controlled substance records.

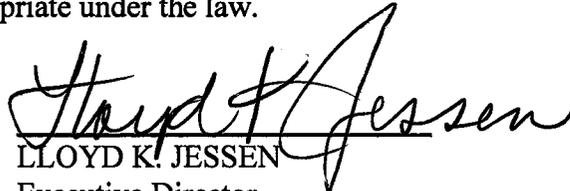
## **B. CIRCUMSTANCES**

An investigation, commenced on April 30, 2009, revealed the following:

1. Respondent is a reverse distributor of drugs. Approximately 10 percent of its activities concern controlled substances, which are either returned to manufacturers or incinerated.
2. An on-site inspection of Respondent in March of 2009 revealed numerous operating deficiencies:
  - a. Schedule II controlled substances, which should be stored in a safe, were stored in a controlled substance cage.
  - b. Evidence of controlled substance destruction, which should have been recorded on a DEA Form 41, was incomplete – partly due to Respondent's failure to include a destruction date on the form. These forms were not filed separately as required by federal regulations.
  - c. Losses of controlled substances, which should have been reported on a DEA Form 106.
  - d. DEA forms 222 were modified by the use of correction fluid and obviously altered counts of controlled substances. These forms were not filed sequentially as required by Board rules.
3. Pharmacy Board compliance officers conducted an audit of the Schedule I and Schedule II controlled substances that have been in Respondent's possession. The audit covered a roughly five month period, from November 7, 2008 to April 17, 2009. The starting date of November 7, 2008 was chosen because Respondent claimed to possess a biennial inventory as of that date. Respondent indicated that its computer system could generate an accurate count of the drug inventory for April 17, 2009, in lieu of a hand count.
4. During the course of the audit, Respondent provided four alleged inventories, each one substantially different from the others.
5. Compliance officers, who spent about 1100 hours completing the audit, found – as to Schedule I and Schedule II controlled substances – Respondent's records establish that for the five month period, Respondent's inventory was short 444,243.8 doses of certain drugs, and long 48,368.9 doses of others. Respondent did not report this shortage of controlled substances to the Board.
6. The audit revealed that some controlled substances received by Respondent in November of 2008 were unaccounted for, in total, by the time of the April audit.
7. The audit also revealed that some controlled substances received in April of 2009 were not shown on Respondent's inventory, nor shown as destroyed, nor shown as returned to a manufacturer. These controlled substances included quantities of oxycodone, hydrocodone and methadone, all of which were received by Respondent on the same day, April 2, 2009.
8. Respondent was also requested to provide an inventory as of April 17, 2009. Respondent provided two different inventories for that date. An audit of Respondent's inventory of Schedule I and Schedule II controlled substances, as of April 17, 2009, revealed Respondent's actual inventory was short 157,054.2 doses of certain drugs, and long 83, 680.61 doses of others.
9. During the time that Compliance Officers were auditing Respondent's records, Respondent repeatedly "found" additional documents in an attempt to reconcile Respondent's records.
10. Respondent acknowledges that its computerized data base was corrupted in January or February of 2009, which fact was not discovered by Respondent until August of 2009.

11. Respondent does not have paper records to support its computerized inventory. Respondent was never able to provide Compliance Officers with a signed copy of the official 2007 biennial inventory.
12. The DEA also conducted an investigation of Respondent in March of 2009. The DEA accountability audit revealed numerous record keeping deficiencies and violations of the Code of Federal Regulations by Respondent. The DEA issued Respondent a warning letter.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

  
 LLOYD K. JESSEN  
 Executive Director

On this 8<sup>th</sup> day of October 2009, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

  
 VERNON BENJAMIN, Chairperson  
 Iowa Board of Pharmacy  
 400 SW Eighth Street, Suite E  
 Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
 Assistant Attorney General  
 Hoover State Office Building  
 Des Moines, Iowa 50319

James Pray  
 Brown Winick  
 666 Grand Avenue, Suite 2000  
 Des Moines, IA 50309-2510

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- |   |   |
|---|---|
| <input type="checkbox"/> personal service                         | <input type="checkbox"/> first class mail |
| <input type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number _____  | <input type="checkbox"/> other _____      |
- on the 9 day of October, 2009.

I declare that the statements above are true to the best of my information, knowledge and belief.

  
 Jean Rhodes

**BEFORE THE BOARD OF PHARMACY  
FOR THE STATE OF IOWA**

Re:	)	
Wholesale Drug License of	)	Case No. 2009-48
<b>NATIONAL PHARMACEUTICAL</b>	)	
<b>RETURN</b>	)	<b>EMERGENCY ORDER</b>
License No. 5261,	)	
Respondent.	)	

**I. JURISDICTION**

The Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over wholesale drug licensees pursuant to Iowa Code Chapters 155A and 272C (2009). National Pharmaceutical Return ("Respondent") possesses wholesale drug license number 5261 issued by the Board. A Statement of Charges was filed against Respondent on October \_\_\_, 2009. After receipt and review of the Statement of Charges, and review of evidence relating to the Statement of Charges, the Board adopts the following Findings of Fact, Conclusions of Law and Emergency Order.

**II. FINDINGS OF FACT**

1. On November 10, 2008, the Board renewed Respondent's wholesale drug license evidenced by license number 5261, subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent is a reverse distributor of drugs. Approximately 10 percent of its activities involve controlled substances, which are either returned to manufacturers or incinerated.
3. An investigation of Respondent commenced on April 30, 2009. The on-site inspection of Respondent in March of 2009 revealed numerous operating deficiencies, including the following:

- a. Schedule II controlled substances, which should be stored in a safe, were stored in a controlled substance cage.
  - b. Evidence of controlled substance destruction, which should have been recorded on a DEA Form 41, was incomplete – partly due to Respondent's failure to include a destruction date on the form. In some cases, the person who signed the form did not participate in the drug destruction. These forms were not filed separately as required by federal regulations.
  - c. Losses of controlled substances should have been reported on a DEA Form 106.
  - d. DEA forms 222 were modified by the use of correction fluid and obviously altered counts of controlled substances. These forms were not filed sequentially as required by Board rules.
4. Pharmacy Board compliance officers conducted an audit of the Schedule I and Schedule II controlled substances that have been in Respondent's possession. The audit covered roughly a five month period, from November 7, 2008 to April 17, 2009. The starting date of November 7, 2008 was chosen because Respondent claimed to possess a biennial inventory as of that date.
  5. During the course of the audit, Respondent provided four alleged inventories for November 7, 2008, each one substantially different from the others. The existence of four inconsistent inventories (for the same period) demonstrates that Respondent has no reliable or real inventory for the year ending November 7, 2008.
  6. Compliance officers, who spent about 1100 hours completing the audit, found – as to Schedule I and Schedule II controlled substances – Respondent's records establish that for

the roughly five month period between November 7, 2008 and April 17, 2009, Respondent's inventory was short 444,243.8 doses of certain drugs, and long 48,368.9 doses of others. Respondent had not reported this shortage of controlled substances to the Board.

7. The audit revealed that some controlled substances received by Respondent in November of 2008 were unaccounted for, in total, by the time of the April audit.
8. The audit also revealed that some controlled substances received in April of 2009 were neither shown on Respondent's inventory, nor shown as destroyed, nor shown as returned to a manufacturer. These controlled substances included quantities of oxycodone, hydrocodone and methadone, all of which were received by Respondent on the same day, April 2, 2009.
9. Respondent was also requested to provide an inventory as of April 17, 2009. Respondent provided two different inventories for that date. A subsequent audit utilizing additional inventories provided by Respondent revealed Respondent was short 157,054.2 doses of certain drugs, and long 83,680.61 doses of others.
10. During the time that Compliance Officers were auditing Respondent's records, Respondent repeatedly "found" additional documents in an attempt to reconcile Respondent's records.
11. Respondent acknowledges that its computerized data base was corrupted in January or February of 2009, which fact was not discovered by Respondent until August of 2009.
12. Respondent does not have paper records to support its computerized inventory. Respondent was never able to provide Compliance Officers with a signed copy of the official 2007 biennial inventory.
13. The DEA also conducted an investigation of Respondent in March of 2009. The DEA accountability audit revealed numerous record keeping deficiencies and violations of the

Code of Federal Regulations. The DEA issued Respondent a warning letter on April 29, 2009.

14. The Board finds that immediate, emergency action must be taken due to Respondent's inadequate record keeping, inadequate security procedures, failure to report controlled substance losses to the Board and non-compliance with federal regulations. The fact that Respondent, in a five month period, cannot account for 444,243 doses of Schedule I and Schedule II controlled substances is evidence of an immediate and substantial danger to the public health, safety and welfare. Some of these unaccounted-for controlled substances – many of which are both powerful and highly addictive – may have been diverted into illegal use.
15. The Board further finds that the massive number of unaccounted for doses of controlled substances – standing alone – suggests that emergency action is needed to alert Respondent to its record-keeping and drug security responsibilities, and to force Respondent to bring its record-keeping and security into compliance with state and federal regulations. It is clear that Respondent has not, voluntarily and without regulatory involvement, achieved compliance with Iowa law and federal regulations relating to Respondent's wholesale drug license.
16. Respondent has been unable to provide the essential information necessary to evaluation of its reverse distribution operation – an accurate inventory. Until an accurate beginning inventory can be established, Respondent cannot achieve compliance with law. In other words, without a valid starting point, future compliance by Respondent cannot be measured, diversion cannot be discovered and confirmed, and the public health, safety and welfare

preserved. Thus, as a practical matter, Respondent must suspend receipt of controlled substances until such time as it is able to accurately account for what it already has in its possession.

17. Emergency action is also called for because Respondent's records indicate that controlled substances are coming into Respondent's possession, but not being posted to an inventory. Drug diversion is likely in this circumstance. Similarly, Respondent's records indicate that some controlled substances are being logged into Respondent's records, but no subsequent record indicates the ultimate disposition of those drugs either by return to the manufacturer or by destruction. This circumstance also indicates diversion is likely.
18. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:
  - a. Immediate suspension of Respondent's authority to accept shipments of controlled substances.
  - b. Issuance of an order directing that Respondent's authority to accept shipments of controlled substances may only be restored at such time as Respondent can establish to the Board's satisfaction that its record keeping procedures are in full compliance with all applicable state and federal laws and regulations, including regulations relating to use of DEA forms 41 and 222.
  - c. Issuance of an order directing that Respondent prepare an inventory, based on a verifiable hand count, of all controlled substances. The inventory shall include the controlled substance name, strength, quantity, dosage form and NDC number, and shall be signed by the person counting the substances. The order shall provide that Respondent shall

complete the inventory within 10 days of the date of the order.

- d. Issuance of an order requiring that Respondent construct or acquire a record-keeping system of sufficient sophistication and scope as to accommodate the business needs of Respondent, and be prepared to demonstrate the functionality of such a system to the Board prior to restoration of Respondent's ability to accept new shipments of controlled substances.

### **III. CONCLUSIONS OF LAW**

1. Respondent's numerous and serious violations of the provisions of Iowa Code chapter 155A (2009), 657 Iowa Administrative Code chapters 17 and 36.1(4)(d), along with violations of federal regulations, prevent Respondent from performing as a wholesale drug licensee in a manner consistent with the public health, safety and welfare.
2. The provisions of Iowa Code § 17A.18A (2009) permit the Board of Pharmacy to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of fact adopted above.

### **IV. EMERGENCY ORDER**

The Board ORDERS as follows:

1. Pursuant to its authority in Iowa Code § 17A.18A, chapter 155A (2009), and 657 Iowa Administrative Code chapters 17 and 36:
  - a. Respondent's authority to accept shipments of controlled substances is hereby suspended.

- b. Respondent's authority to dispose of controlled substances in any manner, including the destruction of controlled substances and the return of controlled substances to manufacturers and others, is hereby suspended.
  - c. Respondent's authority to accept shipments of controlled substances or dispose of them may only be restored at such time as Respondent can establish to the Board's satisfaction that its record-keeping procedures are in full compliance with all applicable state and federal laws and regulations, including regulations relating to use of DEA forms 41 and 222.
  - d. Respondent shall prepare an inventory, based on a verifiable hand count, of all controlled substances. The inventory shall include the substance name, strength, quantity, dosage form and NDC number, and shall be signed by the person counting the substances. Respondent shall complete the inventory within 10 days of the date of this order.
  - e. Respondent shall construct or acquire a record-keeping system of sufficient sophistication and size to accommodate the business needs of Respondent, and be prepared to demonstrate the functionality of such a system to the Board prior to restoration of Respondent's ability to accept new shipments of controlled substances.
2. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on November 18, 2009. The hearing will be held during the morning session beginning at 9:00A.M. and be held at the office of the Iowa Board of Pharmacy, 400 Southwest 8<sup>th</sup> Street, Suite E, Des Moines, Iowa 50309.

**DATED** this 8 day of October 2009.



VERNON BENJAMIN, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- |   |   |
|---|---|
| <input type="checkbox"/> personal service                         | <input type="checkbox"/> first class mail |
| <input type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number _____  | <input type="checkbox"/> other _____      |
- on the 9 day of October, 2009

I declare that the statements above are true to the best of my information, knowledge and belief.



Jean Rhodes

**BEFORE THE IOWA BOARD OF PHARMACY**

Re:	)	
Controlled Substance Registration of:	)	Case No. 2009-48
<b>NATIONAL PHARMACEUTICAL</b>	)	
<b>RETURN,</b>	)	<b>ORDER TO SHOW CAUSE</b>
Registration No. 2210280,	)	
Respondent.	)	

**TO: National Pharmaceutical Return  
4164 N.W Urbandale Drive  
Des Moines, IA 50322**

**NOTICE: Pursuant to the provisions of Iowa Code chapter 124 (2009) and 657 Iowa Administrative Code 10.12(5), you are hereby ordered to appear before the Iowa Board of Pharmacy and show cause why controlled substance registration number 5100247, issued to National Pharmaceutical Return should not be suspended or revoked. IF YOU DESIRE A HEARING REGARDING REVOCATION OF THIS CONTROLLED SUBSTANCE REGISTRATION, YOU MUST FILE A REQUEST FOR A HEARING BEFORE THE BOARD WITHIN THIRTY (30) DAYS OF ISSUANCE OF THIS ORDER.**

**I. JURISDICTION**

Pursuant to Iowa Code Chapter 124 (2009) and 657 Iowa Administrative Code § 10.12(5), the Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over those who manufacture, distribute, and dispense controlled substances in Iowa. Effective November 10, 2008, the Board renewed National Pharmaceutical Return (hereinafter, "Respondent") controlled substance registration number 2210280, subject to the laws of the State of Iowa and the rules of the Board. Respondent is engaged in the business of reverse distribution of drugs, including controlled substances. The business is located at 4146 Northwest Urbandale Drive, Des Moines, IA 50322.

**II. BASIS FOR ORDER TO SHOW CAUSE**

An investigation, commenced on April 30, 2009, revealed the following:

1. Respondent is a reverse distributor of drugs. Approximately 10 percent of its activities

- concern controlled substances, which are either returned to manufacturers or incinerated.
2. An on-site inspection of Respondent in March of 2009 revealed numerous operating deficiencies:
    - a. Schedule II controlled substances, which should be stored in a safe, were stored in a controlled substance cage.
    - b. Evidence of controlled substance destruction, which should have been recorded on a DEA Form 41, was incomplete – partly due to Respondent's failure to include a destruction date on the form. In some cases, the person who signed the form did not participate in the drug destruction. These forms were not filed separately as required by federal regulations.
    - c. Losses of controlled substances, which should have been reported on a DEA Form 106.
    - d. DEA forms 222 were modified by the use of correction fluid and obviously altered counts of controlled substances. These forms were not filed sequentially as required by Board rules.
  3. Board compliance officers conducted an audit of the Schedule I and Schedule II controlled substances that have been in Respondent's possession. The audit covered a roughly five month period, from November 7, 2008 to April 17, 2009. The starting date of November 7, 2008 was chosen because Respondent claimed to possess a biennial inventory as of that date.
  4. During the course of the audit, Respondent provided four alleged inventories, each one substantially different from the others.
  5. Compliance officers, who spent about 1100 hours completing the audit, found – as to Schedule I and Schedule II controlled substances only – Respondent's records establish that

for the five month period, Respondent's inventory was short 444,243.8 doses of certain drugs, and long 48,368.9 doses of others. Respondent did not report this shortage of controlled substances to the Board.

6. The audit revealed that some controlled substances received by Respondent in November of 2008 were unaccounted for, in total, by the time of the April audit.
7. The audit also revealed that some controlled substances received in April of 2009 were not shown on Respondent's inventory, nor shown as destroyed, nor shown as returned to a manufacturer. These controlled substances included quantities of oxycodone, hydrocodone and methadone, all of which were received by Respondent on the same day, April 2, 2009.
8. Respondent was also requested to provide an inventory as of April 17, 2009. Respondent provided two different inventories for that date. An audit of Respondent's inventory of Schedule I and Schedule II controlled substances, as of April 17, 2009, revealed Respondent's actual inventory was short 157,054.2 doses of certain drugs, and long 83,680.61 doses of others.
9. During the time that Compliance Officers were auditing Respondent's records, Respondent repeatedly "found" additional documents in an attempt to reconcile Respondent's records.
10. Respondent acknowledges that its computerized data base was corrupted in January or February of 2009, which fact was not discovered by Respondent until August of 2009.
11. Respondent does not have paper records to support its computerized inventory. Respondent was unable to provide Compliance Officers with a signed copy of the official 2007 biennial inventory.
12. The DEA also conducted an investigation of Respondent in March of 2009. The DEA

accountability audit revealed numerous record keeping deficiencies and violations of the Code of Federal Regulations by Respondent. The DEA issued Respondent a warning letter.

### **III. ORDER**

Respondent National Pharmaceutical Return is hereby ordered to appear before the Iowa Board of Pharmacy and show cause why controlled substance registration number 2210280, issued in its name, should not be suspended or revoked for the reason that Respondent has committed such acts as would render the registration inconsistent with the public interest. If Respondent wishes to have a hearing before the Board in response to this Order, Respondent must notify the Board within thirty (30) days of the date of this Order. Respondent's request for a hearing should be directed to Lloyd Jessen, Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The Board office telephone number is (515) 281-5944.

**IT IS SO ORDERED** this 8<sup>th</sup> day of October 2009.



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VERNON H. BENJAMIN, Chairperson  
Iowa Board of Pharmacy Examiners

cc: Scott Galenbeck, Assistant Iowa Attorney General  
Drug Enforcement Administration, Des Moines  
James Pray, Attorney for Respondent

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- |   |   |
|---|---|
| <input type="checkbox"/> personal service                         | <input type="checkbox"/> first class mail |
| <input type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number _____  | <input type="checkbox"/> other _____      |

on the 9 day of October, 2009

I declare that the statements above are true to the best of my information, knowledge and belief.

  
\_\_\_\_\_  
Jean Rhodes

BEFORE THE IOWA BOARD OF PHARMACY

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Re:  
Wholesale Drug License of

CASE NO. 2009-48  
DIA NO. 09PHB035

NATIONAL PHARMACEUTICAL  
RETURN  
License No. 5261  
RESPONDENT

BOARD RULING DENYING  
RESPONDENT REQUEST  
FOR IMMEDIATE STAY

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On October 8, 2009, the Iowa Board of Pharmacy (Board) found probable cause to file a Statement of Charges, Order to Show Cause, and Emergency Order to National Pharmaceutical Return (Respondent). The Statement of Charges alleged six counts of violations of state and federal statutes and regulations. The Emergency Order, which was issued pursuant to Iowa Code section 17A.18A, Iowa Code chapter 155A and 657 IAC chapters 17 and 36, included Findings of Fact and Conclusions of Law. The Emergency Order immediately suspended Respondent's authority to accept shipments of controlled substances and its authority to dispose of controlled substances in any manner. The Emergency Order further provided, in relevant part, that:

- c. Respondent's authority to accept shipments of controlled substances or to dispose of them may only be restored at such time as Respondent can establish to the Board's satisfaction that its record keeping procedures are in full compliance with all applicable state and federal laws and regulations, including regulations relating to the use of DEA forms 41 and 222.
- d. Respondent shall prepare an inventory, based on a verifiable hand count, of all controlled substances. The inventory shall include the substance name, strength, quantity, dosage form and NDC number, and shall be signed by the person counting the substances. Respondent shall complete the inventory within 10 days of the date of this order.
- e. Respondent shall construct or acquire a record-keeping system of sufficient sophistication and size to accommodate the business needs of Respondent, and be prepared to demonstrate the functionality of such a system to the Board prior to restoration of

Respondent's ability to accept new shipments of controlled substances.

(Emergency Order, p. 7, sections "c"-"e")

On October 14, 2009, Respondent filed a Request for Immediate Stay of the Board's Emergency Order. On October 19, 2009 at 1:45 p.m., Respondent delivered a controlled substance inventory to the Board consisting of over 1400 pages. On October 19, 2009 at 2:15 p.m. the Board convened by telephone conference call to hear testimony and argument on the Request for Immediate Stay. The following members of the Board presided at the motion hearing: Vernon Benjamin, Chairperson; Edward L. Maier; Mark Anliker, Margaret Whitworth, and Ann Diehl. The state was represented by Assistant Attorney General Scott Galenbeck. Respondent was represented by attorney Michael Sellers. The hearing was closed to the public, pursuant to Iowa Code section 272C.6(1) and was recorded by a certified court reporter. Jeff Hollar, Respondent's chief operating officer, provided brief testimony. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was instructed to prepare the Board's Ruling, in conformance with its deliberations and action in open session.

#### ANALYSIS

In determining whether to grant a stay, the board shall consider the extent to which the applicant is likely to prevail when the court finally disposes of the matter, the extent to which the applicant will suffer irreparable injury if relief is not granted, the extent to which the grant of relief to the applicant will substantially harm other parties to the proceedings, and the extent to which the public interest relied on by the board is sufficient to justify the board's action in the circumstances. 657 IAC 35.28(2).

The Board recognizes that the Emergency Order has serious ramifications for Respondent's ongoing business and for its Drug Enforcement Agency (DEA) registration. However, the Board took the emergency action in this case, following careful review and deliberation, because the Board determined that such action was necessary to protect the health, safety and welfare of the public. (Emergency Order, Conclusions of Law)

The Board set out in its Emergency Order, at paragraphs "c"-"e", what showing would be required prior to restoration of Respondent's authority to accept

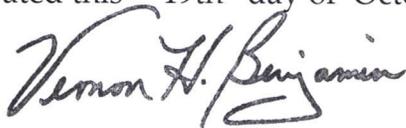
shipments of controlled substances and dispose of controlled substances. Respondent submitted an inventory of its controlled substances, as provided in paragraph "d", immediately prior to the Board's hearing on the stay. However, Board staff has not yet had the opportunity to review the 1400+ pages of the inventory.

Moreover, Respondent has not complied with the requirements of paragraphs "c" and "e" of the Emergency Order. Respondent has not established, to the Board's satisfaction, that its record keeping procedures are in full compliance with all applicable state and federal laws and regulations, including regulations relating to the use of DEA forms 41 and 222. In addition, Respondent has not shown that it has constructed or acquired a record-keeping system of sufficient sophistication and size to accommodate the business needs of Respondent. Based on this record, the Board is not satisfied that the public health, safety, and welfare would be adequately protected if the Emergency Order is stayed.

ORDER

IT IS THEREFORE ORDERED that Respondent's Request for Immediate Stay is hereby DENIED.

Dated this 19th day of October, 2009.



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Vernon Benjamin, Chairperson  
Iowa Board of Pharmacy

cc: Scott Galenbeck, Assistant Attorney General  
Michael Sellers, Respondent's Attorney

BEFORE THE IOWA BOARD OF PHARMACY

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Re:	)	
Wholesale Drug License of	)	Case No. 2009-48
	)	
NATIONAL PHARMACEUTICAL	)	BOARD RULING LIFTING
RETURN	)	EMERGENCY ORDER
License No. 5261,	)	
Respondent.	)	

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On October 8, 2009, the Iowa Board of Pharmacy (Board) found probable cause to file a Statement of Charges, Order to Show Cause, and Emergency Order to National Pharmaceutical Return (Respondent). The Statement of Charges alleged six counts of violations of state and federal statutes and regulations. The Emergency Order, which was issued pursuant to Iowa Code section 17A.18A, Iowa Code chapter 155A and 657 IAC chapters 17 and 36, included Findings of Fact and Conclusions of Law. Respondent is a reverse distributor of drugs, and approximately 10 percent of its activities involve controlled substances, which are either returned to manufacturers or incinerated.

The Emergency Order immediately suspended Respondent's authority to accept shipments of controlled substances and its authority to dispose of controlled substances in any manner. The Emergency Order further provided, in relevant part, that:

- c. Respondent's authority to accept shipments of controlled substances or to dispose of them may only be restored at such time as Respondent can establish to the Board's satisfaction that its record keeping procedures are in full compliance with all applicable state and federal laws and regulations, including regulations relating to the use of DEA forms 41 and 222.
- d. Respondent shall prepare an inventory, based on a verifiable hand count, of all controlled substances. The inventory shall include the substance name, strength, quantity, dosage form and NDC number, and shall be signed by the person counting the substances. Respondent shall complete the inventory within 10 days of the date of this order.
- e. Respondent shall construct or acquire a record-keeping system of sufficient sophistication and size to accommodate the business needs of Respondent, and be prepared to demonstrate the functionality of such a system to the Board prior to restoration of Respondent's ability to accept new shipments of controlled substances.

(Emergency Order, p. 7, sections "c"- "e")

On October 14, 2009, Respondent filed a Request for Immediate Stay of the Board's Emergency Order, which the Board heard and denied on October 19, 2009. On

October 20, 2009, Respondent filed a Second Request for an Emergency Hearing and Immediate Stay.

On October 21, 2009, the Board heard and denied Respondent's Second Request for an Immediate Stay. On October 23, 2009, Respondent filed a Third Request for an Emergency Hearing and Immediate Stay.

On October 28, 2009 at 2:00 p.m. the Board convened by telephone conference call to review steps taken by Respondent to comply with Board's Emergency Order dated October 8, 2009. The following members of the Board presided at the motion hearing: Vernon Benjamin, Chairperson; Edward L. Maier; Mark Anliker, Susan Frey, DeeAnn Wedemeyer Oleson, and Ann Diehl. The teleconference was closed to the public, pursuant to Iowa Code section 272C.6(1) and was recorded by a certified court reporter. Jean Rhodes and Dennis Dobesh, Pharmacy Board Investigators, provided testimony.

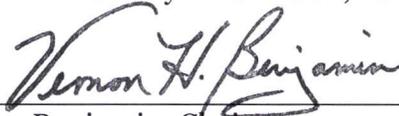
#### ANALYSIS

The Board received and reviewed the following: Respondent's third request for an emergency hearing and immediate stay; a written and oral report from Board compliance officer Jean Rhodes; an oral report from Board compliance officer Dennis Dobesh; and an e-mail and four attachments from Jeff Hollar, the chief operating officer at National Pharmaceutical Returns, Inc. Following review and discussion of this new information, the Board believes that Respondent has now made a good faith effort to comply with the terms of the Emergency Order issued on October 8, 2009. The Board is satisfied that the public health, safety, and welfare would be adequately protected if the Emergency Order is lifted.

#### ORDER

IT IS THEREFORE ORDERED that Respondent's Third Request for Immediate Stay is hereby GRANTED. The Emergency Order issued on October 8, 2009, is hereby LIFTED. The Statement of Charges issued to Respondent on October 8, 2009, shall be resolved by either an administrative hearing before the Board or by way of an informal settlement or Stipulation/Consent Agreement.

Dated this 28<sup>th</sup> day of October , 2009.



Vernon Benjamin, Chairperson  
Iowa Board of Pharmacy

cc: Scott Galenbeck, Assistant Attorney General  
Michael Sellers, Respondent's Attorney

**BEFORE THE IOWA BOARD OF PHARMACY**

Re:	)	Case No. 2009-48
Wholesale Drug License of	)	
<b>NATIONAL PHARMACEUTICAL</b>	)	<b>STIPULATION</b>
<b>RETURNS, INC.</b>	)	<b>AND</b>
License No. 5261	)	<b>CONSENT ORDER</b>
Respondent	)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, the "Board") and National Pharmaceutical Returns, Inc. (hereinafter, "Respondent"), enter into the following Stipulation and Consent Order settling a licensee disciplinary proceeding currently pending before the Board.

Allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent's wholesale drug license number 5261, as recorded in the permanent records of the Board is current and active until December 31, 2011.
2. The Board has jurisdiction over the parties and the subject matter of this disciplinary proceeding.
3. A Statement of Charges and an Emergency Order were filed against Respondent on October 8, 2009.
4. Although Respondent disputes the allegations contained in the Statement of Charges, Respondent has chosen not to contest these allegations. Respondent acknowledges that the allegations of the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

5. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall do the following:

(a) Within sixty (60) days after the date of the Board's approval of this Stipulation and Consent Order, Respondent will propose to the Board written pharmacy policies and procedures covering, but not limited to, the following topics: (1) receipt and handling of controlled substances, (2) monitoring personnel who handle controlled substances, (3) prevention of drug diversion, (4) security of all prescription medications, (5) accurate records and accountability for controlled substances, (6) destruction and disposal of outdated, returned and/or unwanted controlled substances, and (7) appropriate responses to evidence of employee substance abuse or impairment. Following review and approval by the Board, Respondent agrees to adopt, implement, and adhere to these policies and procedures.

(b) Respondent shall obey all federal and state laws, rules, and regulations substantially related to Respondent's wholesale drug license.

(c) Respondent shall submit to and must pass three consecutive annual inspections and audits, commencing in the year following approval of this Stipulation and Consent Order. The inspections and audits will be conducted by the Board's compliance officers.

6. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall promptly mail to the executive director of the Board, pursuant to the provisions of Iowa Code 155A.18, a check in the amount of \$7,500 made payable to the Treasurer of

Iowa. The payment shall be deposited into the State of Iowa general fund.

7. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate further action to impose licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

8. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

9. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

10. The State's counsel may present this Stipulation and Consent Order to the Board.

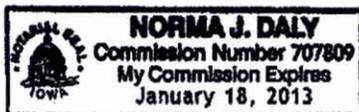
11. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER.

This Stipulation and Consent Order is voluntarily submitted by Respondent to the Iowa Board of Pharmacy for its consideration on this 1 day of June 2011.

  
NATIONAL PHARMACEUTICAL  
RETURNS, INC., Respondent  
By Amber Hollar, CEO

Subscribed and sworn to before me by Amber Hollar, who has stated to me that she is authorized

to sign this Stipulation and Consent Order on behalf of National Pharmaceutical Returns, Inc., on this 1st day of June 2011.



Norma Daly  
NOTARY PUBLIC IN AND FOR THE  
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 10<sup>th</sup> day of August 2011.

Susan M. Frey  
SUSAN FREY, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

Mike Sellers  
400 Locust Street  
Suite 170  
Des Moines, Iowa 50309

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