



STATE OF MARYLAND

**DHMH**

Department of Health and Mental Hygiene

*Lawrence J. Hogan, Jr. Governor – Boyd K. Rutherford, Lt. Governor – Van T. Mitchell,  
Secretary*

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**MARYLAND BOARD OF PHARMACY**

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

*Lenna Israbian-Jamgochian, Board President - LaVerne G. Naesea, Executive Director*

**VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED**  
**ARTICLE #7014 0510 0001 0445 0613**

May 14, 2015

Ibex Dead Sea Imports  
11520 Rockville Pike  
Rockville, Maryland 20850  
Attn: Shay Zahari, R.Ph.

Re: Permit No. P05899  
Notice of Deficiencies, Recommended Civil Monetary Penalty, and  
Opportunity for Hearing

Dear Pharmacist Zahari:

On February 5, 2015, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Ibex Dead Sea Imports (the "Pharmacy") for compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated that the Pharmacy was not compliant with laws relating to pharmacy technician registration. Specifically, the Board inspector observed an individual performing delegated pharmacy acts who was not duly registered with the Board as a pharmacy technician. The Board's records indicate that subject individual subsequently submitted an application for registration although the application is still pending review.

#### **I. FINDINGS AND CONCLUSION**

The Board adopts as findings the deficiencies as stated in the Board's inspection report, dated February 5, 2015, and attached hereto as Exhibit A.

Based upon deficiencies at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(b)(1) and 12-6B-01.

410-764-4755 • Fax 410-384-4128 ext. 500 • Toll Free 800-542-4964

DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258

Web Site: [www.dhmh.maryland.gov/pharmacy](http://www.dhmh.maryland.gov/pharmacy)

## II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in the Board's inspection report dated February 5, 2015.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

## III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to insure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

## IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 *et seq.*, and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Vanessa Thomas Gray, Compliance Investigator, Maryland Board of Pharmacy, 4201 Patterson Ave., 1<sup>st</sup> Floor, Baltimore, Maryland 21215, **no later than thirty (30) days of the date of this Notice.**

Please be advised that at the hearing you would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on your own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports, the Board may suspend or revoke the pharmacy permit, or impose civil penalties, or both.

If you request a hearing but fail to appear, the Board may nevertheless hear and determine the matter in your absence.

**V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY**

Alternatively, the Pharmacy may pay the recommended civil monetary penalty **within thirty (30) days** of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy. Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the inspection report dated, February 5, 2015, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas Gray, Compliance Investigator, at 410-764-2493.

Sincerely,



LaVerne G. Naesea  
Executive Director

cc: Linda Bethman, Board Counsel



STATE OF MARYLAND

Exhibit

DHMH

Maryland Department of Health and Mental Hygiene  
Lawrence J Hogan Jr Governor -- Boyd K

3  
Tech. No License  
2/23/2015

A  
Certified Tech. / Not registered.  
CAS  
Tech initials on label  
procedure report med errors.  
2 yrs training

2/24/15  
N. Richard

COMMUNITY PHARMACY

Corporate Pharmacy Name \_\_\_\_\_  
Pharmacy Name-Doing Business as (d/b/a) or Trade \_\_\_\_\_  
Street Address 11520 Rockville Pike, Rockville, Maryland  
Business Telephone Number 301-881-1555 Busi \_\_\_\_\_  
Inspection Date: 2/5/2015 Arrival Time: 1:45  
Type of Inspection:  Annual  Follow-up  
Name of Inspector: Shanelle Young

I. GENERAL INFORMATION

Yes  No  The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment.

Pharmacy Hours M-F: 9am-8:45pm Sat: 10am-2pm Sun: Closed

Yes  No  All permits, licenses, and registrations are posted conspicuously. HO § 12-311, HO § 12-408(b) and HO § 12-6B-08

Maryland Pharmacy Permit Number P05899 Expiration Date: 5/31/2016  
CDS Registration Number 477155 Expiration Date: \_\_\_\_\_  
DEA Registration Number F13691448 Expiration Date: 11/30/2015

Yes  No  The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

Yes  No  The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23

Yes  No  The pharmacy fills original prescriptions received via the internet.

Yes  No  The pharmacy fills original prescriptions via e-prescribing.

Yes  No  The pharmacist fills mail order prescriptions.

If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07

Comments:

There are no closing hours posted for Saturdays. CDS expiration date was extended per DDC (See attached letter from DDC). Pharmacist calls to verify original prescriptions sent via e-prescribing.



3. PERSONNEL TRAINING

Yes  No  N/A  There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03 and 10.34.21.05

Yes  No  N/A  All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B(3) and (4)

- Yes  No  N/A  Maintaining records
- Yes  No  N/A  Patient confidentiality
- Yes  No  N/A  Sanitation, hygiene, infection control
- Yes  No  N/A  Biohazard precautions
- Yes  No  N/A  Patient safety and medication errors COMAR 10.34.26.03

Comments:

Need documentation of training for each staff member including unlicensed personnel.

Yes  No  The pharmacy wholesale distributes to another pharmacy (COMAR 10.34.37)

Yes  No  The pharmacy wholesale distributes to a wholesale distributor (COMAR 10.34.37)

Yes  No  N/A  The wholesale distribution business exceeds 5% of the pharmacy annual sales (COMAR 10.34.37)

Comments:

N/A. The pharmacy does not wholesale distribute per Andrew Kim, Staff Pharmacist.

4. SECURITY COMAR 10.34.05

Yes  No  The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

Comments:

N/A. The pharmacy area closes at the same time as the front store area.

Yes  No  The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Yes  No  The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)

Comments: \_\_\_\_\_

Ok. \_\_\_\_\_

### 5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes  No  Pharmacy area is clean and orderly. HO § 12-403(b) (1) (ii)2.

Yes  No  The pharmacy provides a compounding service (non-sterile procedures).

Yes  No  If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02

Yes  No  The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A

Yes  No  The pharmacy has hot and cold running water.

Yes  No  The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B

Yes  No  The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B

Temperature <sup>46F</sup> \_\_\_\_\_

Yes  No  The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature <sup>76F</sup> \_\_\_\_\_

Yes  No  N/A  If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.

Temperature <sup>1F</sup> \_\_\_\_\_

Yes  No  The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)

Yes  No  The pharmacy has online resources. HO § 12-403(b)(15)

Comments: \_\_\_\_\_

Ok. \_\_\_\_\_

## 6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes  No  Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)

The following label requirements are met if a drug is dispensed pursuant to a prescription: HO § 12-505

- |   |                             |  |
|---|-----------------------------|--|
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name and address of the pharmacy; HG § 21-221(a)(1)                        |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The serial number of the prescription; HG § 21-221(a)(2)                       |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The date the prescription was filled; HO § 12-505(b)(1) and HG § 21-221(a)(3)  |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name of the prescriber; HG § 21-221(a)(4)                                  |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name of the patient; HG § 21-221(a)(5)(i)                                  |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name and strength of the drug or devices; HO § 12-505(c)                   |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The directions for use; HO § 12-505(b)(2)(ii) and HG § 21-221(a)(5)(ii)        |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)      |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The expiration date is indicated; HO § 12-505(b)(2)                            |

Yes  No  The pharmacist and data-entry technician initials are on prescriptions. COMAR 10.34.08.01

Yes  No  Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

### Comments:

Need technician's initials on pharmacy labels.

## 7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes  No  There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider. COMAR 10.34.26.02

Yes  No  The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

Yes  No  There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

### Comments:

Need procedure that tells patients what to do if they suspect a med error handed to each patient or posted in the pharmacy. Need documented training for preventing med errors for each staff member.



Yes  No  All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)

Yes  No  The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)

**Comments:**

The pharmacy does not have a biennial inventory, they have not been open for 2 years yet. There was no beginning controlled inventory taken. Beginning CII inventory for Hydrocodone was taken on 10/6/2014. Beginning controlled inventory for Tramadol was taken today, 2/5/2015.

**11. AUTOMATED MEDICATION SYSTEMS** Yes  No  (if No, go to #12)

Yes  No  N/A  The facility uses an automated device(s) as defined in COMAR 10.34.28.02.

Policies and procedures exist for (check all that apply): COMAR 10.34.28.04A

- Yes  No  N/A  Operation of the system
- Yes  No  N/A  Training of personnel using the system
- Yes  No  N/A  Operations during system downtime
- Yes  No  N/A  Control of access to the device
- Yes  No  N/A  Accounting for medication added and removed from the system.

Yes  No  N/A  Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safe guards. COMAR 10.34.28.06

Adequate records are maintained for at least two years addressing the following (check all that apply).  
COMAR 10.34.28.11

- Yes  No  N/A  Maintenance records.
- Yes  No  N/A  System failure reports.
- Yes  No  N/A  Accuracy audits.
- Yes  No  N/A  Quality Assurance Reports.
- Yes  No  N/A  Reports on system access and changes in access.
- Yes  No  N/A  Training records.

Yes  No  N/A  Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B

Yes  No  N/A  The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

**Comments:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

12. OUTSOURCING

Yes  No  (if No, go to #13)

Yes  No  N/A

The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02

Yes  No  N/A

The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02

Yes  No  N/A

The facility serves as a secondary pharmacy. COMAR 10.34.04.02

Yes  No  N/A

The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.

If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: COMAR 10.34.04.06E

Comments:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Yes  No  N/A

The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)

If the pharmacy outsources a prescription order:

Yes  No  N/A

The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D

Yes  No  N/A

Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06

Yes  No  N/A

Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner: COMAR 10.34.04.06 (Check all that apply)

Yes  No  N/A

That the prescription order was prepared by a secondary pharmacy.

Yes  No  N/A

The name of the secondary pharmacy.

Yes  No  N/A

The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.

Yes  No  N/A

The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.

Yes  No  N/A

The date on which the prescription order was transmitted to the secondary pharmacy.

Yes  No  N/A

The date on which the medication was sent to the primary pharmacy.

Yes  No  N/A

The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F

Yes  No  N/A

The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes: COMAR 10.34.04.07 (Check all that apply)

- Yes  No  N/A  That the prescription order was transmitted from another pharmacy.
- Yes  No  N/A  The name and information identifying the specific location of the primary pharmacy.
- Yes  No  N/A  The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
- Yes  No  N/A  The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- Yes  No  N/A  The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
- Yes  No  N/A  The date on which the prescription order was received at the secondary pharmacy.
- Yes  No  N/A  The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

**13. Recommended Best Practices**

- Yes  No  A perpetual inventory is maintained for Schedule II controlled substances.
- Yes  No  There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
- Yes  No  The pharmacy has written policies and procedures for the safe handling of drug recalls. See [www.recalls.gov](http://www.recalls.gov)
- Yes  No  The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)

**INSPECTOR'S COMMENTS:**

Reviewed inspection form with Shay Zahari, Pharmacy Manager. Checked perpetual inventory (in computer system), no discrepancies found. There were no outdated or mis-labeled items found during check of pharmacy's inventory. Written policies and procedures are found on the pharmacy's intranet. The quality assurance program is documented online through "Evernote". There was no documentation of training to review at the time of inspection. Action suggested per this inspection: 1) Ensure certified technician Leila Sasanpour registers with the Board of Pharmacy ASAP. 2) Ensure closing hours for Saturdays are posted conspicuously. 3) Ensure each staff member including clerk has documented training (section #3). 4) Ensure technician's initials appear on pharmacy label or in computer system. 5) Ensure patient procedures to report suspected medication errors is posted conspicuously in the pharmacy. 6) Ensure each staff member that fills or counts prescriptions have documented training in preventing medication errors. 7) Send proof of MD technician registration, documented training for each staff member (section 3), proof of correction of tech initials on pharmacy's label, patient procedures to report a suspected med error and training for each staff member in preventing medication errors to the Board of Pharmacy Attention Shanelle Young by 2/12/2015.

Inspector Signature Shanelle Young  
 Pharmacist Name ((Print): Shay Zahari Date: 2/5/2015  
 Signature: \_\_\_\_\_  
 Received a copy of this inspection report: \_\_\_\_\_  
*Date and Pharmacist Signature*

FINAL 09/02/2014

CLEAR FORM

PRINT FORM

# CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: IBEX Pharmacy  
 Permit#: P05899  
 Date: 2/5/2015  
 Pharmacist Signature: \_\_\_\_\_

Rx# 113-687N00

DRUGS	ON HAND INVENTORY	PERPETUAL INVENTORY
Opana ER 5mg	83	83
Morphine Sulfate IR 30mg	180	180
Oxycontin 20mg	398	398
Methylphenidate ER 36mg	140	140

COMMENTS:

### PHARMACY LABEL

**IBEX PHARMACY**      DEA: FI3691448  
 11520 E ROCKVILLE PIKE      PH: (301) 881-1555  
 ROCKVILLE, MD 20852      Fax: (301)-881-1599  
 Rx113-691 00 Dr MAZGAJ, M

**IBEX PHARMACY**      DEA: FI3691448  
 11520 E ROCKVILLE PIKE      PH: (301) 881-1555  
 ROCKVILLE, MD 20852      Fax: (301)-881-1599  
 Rx113-687N00 Dr RAO, N

ONE TABLET BY MOUTH THREE  
 TIMES A DAY

ONE TABLET BY MOUTH EVERY 4  
 -6 HOURS AS NEEDED FOR PAIN

DUEXIS      TAB 800-      Exp: 02/05/2016  
 Qty: 90  
 HORIZON PH      SZ  
 Refills left: No 02/05/15 \*COB\*

OXYCODONE      TAB 30MG      Qty: 120  
 Refills left: No 02/05/15 610279  
 SZ

### INVOICE REVIEW

CII:  
 Ok.  
 CIII - CV:  
 Ok.

### PRESCRIPTION REVIEW

CII # 113-268N00-113-500N00  
 DATE: 1/20/2015-1/28/2015

COMMENTS:  
 Ok.

CIII - CV # 113-501-113-599  
 DATE: 2/2/2015-2/28/2015

COMMENTS:  
 Rx 113-562C00, prescriber's DEA number not on hard copy.