

Ken Lawson, Secretary

Rick Scott, Governor

AGENDA
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council
Conference Call

May 17, 2012
9:30 a.m.

Conference Call Number 888-808-6959
Conference Code 6623823948

Council Members:

Gary Cacciatore, Pharm.D., J.D., Chair, Primary Prescription
Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Albert Garcia, Board of Pharmacy
Joseph Brecko, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Karen Zeiler, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Vacant, Physician

DBPR Staff:

Reggie Dixon, Executive Director,
Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Mike Walker, Deputy Secretary
Robert Jernigan, Compliance Manager
Dinah Skrnich, Controlled Substance Reporting
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order and Introductions: Gary Cacciatore, Chair

- TAB 1:** Approval of Minutes
- TAB 2:** Chair's Report – Gary Cacciatore, PharmD, JD
1. Wholesale Distribution of Prescription Drugs-Exceptions and Specific Distributions Authorized
 2. Federal Pedigree
- TAB 3:** Executive Director's Report – Reginald Dixon
1. Returns Rule
 2. 2012 Legislation Affecting Drugs, Device and Cosmetics Program
 3. PIS- Renewals
 4. Hospitals and Repackager
 5. Kudos
- TAB 4:** Controlled Substance Reporting – Kristen Grosh
- TAB 5:** Other Business

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Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**Drugs, Devices and Cosmetics**

The Drug Wholesale Distributor Advisory Council announces a telephone conference call to which all persons are invited.

DATE AND TIME: May 17, 2012 at 9:30 a.m.

PLACE: Conference Call Number 1-888-808-6959

Conference Code: 6623823948

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business

A copy of the agenda may be obtained by contacting: A copy of the agenda can be obtained 7 days prior to the meeting at the below website: http://www.myfloridalicense.com/dbpr/ddc/council_meeting.html

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Drugs, Devices and Cosmetics Program at 850-717-1800. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Drugs, Devices and Cosmetics Program

1940 N. Monroe Street, Suite 26A

Tallahassee, FL 32399-1047, or 850-717-1800

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TAB 1. APPROVAL OF MINUTES

**Drug Wholesale Distributor Advisory Council Meeting
February 16, 2012
Draft Meeting Minutes**

9:30 a.m. Call to Order by Gary Cacciatore, Chair

The meeting was called to order by the Chair, Mr. Cacciatore.

Roll Call taken by Dinah Skrnich.

The following council members were present:

Mr. Cacciatore, Mr. Ayotte, Mr., Brecko, Mr. Ellis, Mr. Garcia, Mr. Mahoney, Mr. Barnes, Ms. Elliott., Mr. Brock.

The following council members were absent: Dr. Walker

A quorum was present

Tab 1. Approval of December 6, 2011 Meeting Minutes

Motion by: Mr. Barnes and seconded by Mr. Ayotte to approve the minutes. Motion Carried.

Tab 2: Returns:

Mr. Cacciatore stated that he added this to the agenda for review and to reintroduce the language for the return rule and asked the department to move forward with noticing the rule for development.

Mr. Dix stated when this was discussed before language was presented allowing returns for the chain pharmacies to return to the chain pharmacy warehouses without any time limit because it was within their own system and control. They also received the drugs with direct purchase pedigree so there was no way to create a full pedigree if they need to be redistributed.

Mr. Dix stated the rule has language regarding "a shipment" being returned he suggested that the department may want to add different language because you may not want to return a whole shipment.

Mr. Ayotte asked could we do a rule to define shipment.

Mr. Dixon stated he can research this and come back with language for the council to review.

Motion by: Mr. Barnes recommended the department begin rule making for 61N-1. 012(3) (f) Returns, seconded by Mr. Brock motion carried.

45
46
47
48 **Tab 3: Federal Pedigree Legislation**
49

50 Mr. Cacciatore stated this is a standing item on the agenda to monitor the federal
51 legislation.

52
53 Mr. Ayotte stated there is a tremendous amount of work going on with this. After the
54 recent notification on the counterfeit Avastin, the cancer drug there will be a more
55 strong and robust movement for this legislation.
56

57 Mr. Cacciatore stated perhaps by the next meeting a bill will be introduced for the
58 council to review.
59

60 **Tab 4: Executive Director's report**
61

62 Mr. Dixon introduced the DDC attorneys Kathryn Price and Bart Moore to the Council.
63

64 Mr. Dixon gave an update to the council on follow up issues from the stakeholder list:

- | | |
|------------------------------------|----------------------------|
| 65 a. Trade secret data | e. Compounding |
| 66 b. List of wholesaler licensees | f. Pedigree Authentication |
| 67 c. Blood Establishment | g. Common Control |
| 68 d. Bond Requirement | |
- 69

70 Mr. Dixon provided the council with an update to the legislative session.
71

72 **Senate Bill 1006**
73

74 The proposed bill creates a license by endorsement, which would only be issued if the
75 applicant demonstrated compliance with the "requirements of this chapter and holds a
76 valid drug wholesale distribution license or permit from another state." The effective
77 date of the bill is July 1, 2012. There is a companion bill for this House Bill 751 that has
78 more language. The department will continue to follow this through the legislative
79 process.
80

81 **House Bill 751**

82 The proposed bill amends Chapter 499, Florida Statutes modifying existing restrictions
83 on the limited distribution of active pharmaceutical ingredients to Florida to licensed
84 prescription drug manufacturers, and restrictions on prescription drug distributions to
85 licensed prescription drug manufacturers and researchers. The proposed bill revises
86 certain definitions and organizes the various exceptions to licensure in Chapter 499,
87 Florida Statutes into a single subsection.
88

89 One of the amendments was if a wholesaler has out sourced the receipts of
90 payments to a payment center. The department made suggestions to the language
91 for distribution to include a payment center under that license.
92

93 Mr. Kahan stated in the discussion of API back in 2010 there was discussion
94 regarding research and development use of API and the amount or quantity that
95 could be purchased.
96

97 Mr. Dixon stated it does not resolve the amount issue but it does open up the
98 sources of where the API could be obtained.
99

100 Mr. Kahan inquired if anything was being done now to address this?
101

102 Mr. Dixon stated to his knowledge nothing but the department could do research and
103 bring it back to the next meeting.
104
105

106 **House Bill 475** 107

108 The bill exempts certain blood establishments from requirements to be permitted as
109 a prescription drug manufacturer and to register products and authorizes DBPR to
110 adopt rules regarding distribution of prescription drugs by blood establishments.
111

112 Mr. Cacciatore asked if this bill passes will the Department have to develop a list of
113 approved drugs that they can distribute under this permit.
114

115 Mr. Dixon stated that is correct.
116

117 **Rules Report:** 118

119 Mr. Dixon advised the council that the DDC rules have been transferred to the
120 department. Mr. Dixon suggested to the council that we start fresh for any rule
121 changes the council suggests from this point forward.
122

123 The council agreed.
124

125 Mr. Dixon stated the DDC rules formerly under 64F-12 have now been transferred to
126 61N-1. The Department of State was accommodating with letting the department
127 keep the actual rule numbers.
128

129 **Process Improvements**

130 Mr. Dixon stated that the program office wanted to share the goals and objectives for
131 the year with the council. Two major goals for this year for DDC are to: 1.) Increase
132 program efficiency and 2.) Improve program effectiveness.

133 These goals will be met by employee training, risk based inspections, balancing the
134 territory inspection maps and performance measures.

135
136 Mr. Dixon stated we are testing risk based inspections in the field now. What this
137 means is the low risk licenses where you there less likely to be diversion of drugs
138 are inspected less frequently and the higher risk facilities are inspected on a more
139 frequent basis. There has been some positive feedback from the industry.

140
141 Mr. Dixon stated in regards to the Controlled Substance Reporting there is a letter in
142 your agenda packet for you to review and approve that will be mailed to the industry.

143
144 Mr. Ellis asked if the letter had been mailed yet.

145
146 Mr. Dixon stated it had not been mailed because the office wanted to let the council
147 review it before being mailed.

148
149 Mr. Cacciatore stated he wanted to thank Mr. Dixon for all his efforts and that he
150 thinks this is a good approach with the risk based inspections.

151 152 **Senate Bill 1316**

153
154 Mr. Dixon stated this bill changes the way inventory is kept for the 340B program.
155 Florida is the only state that requires physical separation of 340B program drugs.
156 This will remove that separate inventory requirement.

157
158 Mr. Barnes asked for clarification on a "bill to ship to" arrangement Where a hospital
159 is buying the product (under 340B pricing) and having the inventory replaced at a
160 contract pharmacy that is not on premises of the hospital. When that occurs since
161 the hospital is the title holder of drugs, is there a pedigree involved in that
162 transaction to the contracted pharmacy?

163
164 Mr. Dixon stated he could not answer that question at this time.

165
166 Mr. Dixon stated a lot of the issues brought to our attention were the facilities had to
167 order the drug then wait for the drug to come in before you could ship that drug out.
168 You could go ahead and send it out without having to wait. When the legislative bill
169 was reviewed the department did not have any concerns with it.

170
171 Mr. Dix stated it is listed under the definition of exemption of wholesale distribution
172 so there is no pedigree requirement.

173 174 **Tab 5 Controlled Substance Reporting**

175
176 Ms. Grosh provided an update to the council on the controlled substance reporting.

177 Ms. Grosh reported that this quarter the department wants to start the data entry
178 screen for the smaller companies that only report a small amount of items or have
179 nothing to report. This summer the department is hoping to have the FTP site ready
180 for submitting reports.
181

182
183 Mr. Cacciatore stated he has a question in regard to the industry compliance letter. If
184 a wholesaler does not have a DEA registration number are they required to report?
185

186 Mr. Ellis stated according to the letter you have to meet both of those requirements.
187 If you don't meet both then you don't have to report.
188

189 Mr. Rodney Bias with PSS World Medical stated he interrupted it the same way. If
190 you have prescription drug wholesale distributor permit you had to report. All of our
191 locations but one don't have DEA license. If the letter is correct it would mean the
192 one location with a DEA license would have to report.
193

194 Mr. Dixon stated we are conducting some research on this because there have been
195 some controlled substances in Florida that are not controlled substances by DEA.
196

197 Mr. Cacciatore stated I have one more question on corrections. The way corrections
198 are handled for Florida reporting is different then ARCOS is there a reason for that?
199

200 Ms. Grosh stated you have to report more information to us then ARCOS, that's why
201 we had to come up with our own correction number independent of ARCOS.
202

203 204 **Tab 6 Other Business**

205 Mr. Barnes gave a presentation on repackaged products as found in the meeting
206 materials and asked the council to re-review the material and have discussion.
207

208 Mr. Dixon asked Mr. Barnes if he is looking for a solution for the hospital to purchase
209 from the wholesaler verses the manufacturer.
210

211 Mr. Barnes stated that is correct.
212

213 Mr. Dixon stated he is conducting some research on repackaging so he can look into
214 this and bring it back to the council.
215

216 Ms. Cacciatore asked if there was any other business.
217

218 **Audience Comments:**

219 Ms. Veronica Clifford presented language to the council in regards to 61N-1.105
220 Licensing, Application, Permitting.

221
222 (11) PERMIT RENEWALS FOR PRESCRIPTION DRUG WHOLESALER,
223 PRESCRIPTION DRUG WHOLESALER – BROKER ONLY, OR OUT-OF-STATE
224 PRESCRIPTION DRUG WHOLESALER.

225 (a) The program will mail an application for renewal of the prescription drug
226 wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription
227 drug wholesaler permit at least 90 days prior to the expiration date of the permit.

228 (b) A renewal application that is postmarked within 45 days prior to the expiration
229 date of the permit must include submission of a \$100 delinquent fee in addition to
230 the annual permit fee, fingerprint fees, and bond.

231 (c) File with the department a completed application for a permit using an original
232 Form DH 2124, "Prescription Drug Wholesaler/Out-of-State Prescription Drug
233 Wholesaler Application" effective January 2004.

234 (d) File with the department an original Form DH 2125, "Personal Information
235 Statement" effective January 2004, for the applicant's manager, next four highest
236 ranking employees that are responsible for prescription drug operations, and all
237 affiliated parties. In the event that there has been no change in any of the items or
238 responses to questions from the Personal Information Statement together with an
239 original affidavit attached thereto which incorporates the Personal Information
240 Statement by reference and states that the information contained therein continues
241 to be true and correct.

242
243 Mr. Cacciatore thanked Ms. Clifford for the language and asked if the department
244 had the authority to make the change.

245
246 Mr. Dixon stated if the council will vote on this recommendation we can asked the
247 attorneys for an opinion.

248
249 **Motion by:** Mr. Cacciatore asked that the language be presented to the department
250 attorneys for review and provide feedback to the council, seconded by Mr. Mahoney.
251 Motion Carried

252
253 Ms. Shannon Salimoney with Holland & Knight asked the council to provide some
254 clarification. There are a number of licenses that are available to in-state
255 wholesalers or other types of drug distributors and not a corresponding out of state
256 license. Is there some general policy decision behind that and has the council made
257 any sort of policy recommendation with respect to why there is such a distinction to
258 some of the licensure categories?

259
260 Mr. Dixon indicated that he could not speak for the council, but that some of the
261 concern probably pertained to the department's authority to do inspections of
262 licensees that did not reside in this state.

264 Mr. Cacciatore stated he doesn't recall the Council has having that discussion for a
265 statute change.

266
267 Mr. Steve Miller with Air Liquide asked if this would be the forum that his company
268 would use to bring issues to regarding medical gases and any changes regarding
269 rules.

270
271 Mr. Dixon indicated that the department would meet with anyone who has any
272 issues or suggested changes to rules.

273
274 Mr. Cacciatore asked if there was any further discussion or business.

275
276 Meeting adjourned 11:40 a.m.
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TAB 2. CHAIR'S REPORT- GARY CACCIATORE

1. WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS-EXCEPTIONS
AND SPECIFIC DISTRIBUTIONS AUTHORIZED
2. FEDERAL PEDIGREE

Skrnich, Dinah

From: Cacciatore, Gary [Gary.Cacciatore@cardinalhealth.com]
Sent: Friday, March 23, 2012 9:33 AM
To: Dixon, Reggie; Jernigan, Robert
Cc: Skrnich, Dinah
Subject: Item for Next DWDAC Meeting

Reggie and Rob,

I would like to add the following item for discussion at the next DWDAC meeting as new business:

Process to get an exemption from pedigree requirements for business continuity purposes.

The purpose is to discuss the need for such an exemption not only for statewide emergencies, but also for individual businesses that may be impacted by unforeseen issues such as a fire which may not qualify for any temporary exemption issued by the Governor's office.

Thanks,

Gary

Gary Cacciatore, Pharm.D., J.D.
Vice President of Regulatory Affairs
and Associate Chief Regulatory Counsel
Cardinal Health
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Houston, TX 77077
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Definition of Wholesale Distribution and Exemptions

499.003(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.
2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.
4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:
 - a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.
 - b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.
 - c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.
 - d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.
 - e. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.
 - f. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity.

The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under subparagraph e.

g. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.
2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.
3. The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider’s license under chapter 401.
4. The revocation of a sale or the return of a prescription drug to the person’s prescription drug wholesale supplier.
5. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.
6. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.
7. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

- (c) The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.
- (d) The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.
- (e) The lawful dispensing of a prescription drug in accordance with chapter 465.
- (f) The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

The rules go on to *further* define what the term "emergency medical reasons" includes:

61N-1.011 Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized.

(1) The exemption from the definition of wholesale distribution in Section 499.003(53)(b)2., F.S., for "emergency medical reasons" includes:

(a) Transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, and should not occur between the parties so as to amount to the health care entity regularly and systematically supplying that drug;

(b) Transfers of prescription drugs by a health care entity to an emergency transport vehicle which is under the direction of a medical director of an emergency medical service provider licensed under Chapter 401, F.S., for use in the treatment of persons transported to that health care entity to immediately restock a licensed vehicle or an emergency medical kit for prescription drugs used on that person or to immediately restock prescription drugs on the vehicle which have become unsuitable for use. This exception does not extend to the stocking of supply inventory or for warehousing of prescription drugs used by emergency medical service providers;

(c) Emergency transfers of prescription drugs as authorized in Rule 59A-4.112, F.A.C., for nursing homes or Rule 64B16-28.6021, F.A.C., of the Florida Board of Pharmacy; or

(d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy or to a health care entity to alleviate a temporary shortage, but not for the regular and systematic supplying of that prescription drug;

(e) Transfers of prescription drugs in an emergency declared pursuant to Section 252.36, F.S., until the state of emergency is lifted, under the following conditions:

1. The manufacturer, wholesaler, or other person supplying the prescription drugs is authorized by Florida law to distribute prescription drugs in or into Florida; and

2. The prescription drugs are delivered to a temporary emergency medical station, officially designated by the state emergency operation center as a Disaster Medical Assistance Team or State Medical Response Team site;

3. The prescription drugs are delivered to a Pharmacy licensed under Chapter 465, F.S.;

(f) Transfers of prescription drugs from a health care entity to a pharmacy or other end-user practitioner for a named patient to treat or prevent a serious medical condition when a shortage of the product is documented by the manufacturer;

but does not include regular and systematic sales of prescription drugs to licensed practitioners that will be used for routine office procedures.

(g) Transfers of prescription drugs by or on behalf of the Department of Health to the medical director of an advanced life support service provider, licensed under Chapter 401, Part III, F.S., and for further distribution to an emergency transport vehicle operated by the advanced life support services provider, for use in the treatment of persons in need of emergency medical services;

(h) Transfers of prescription drugs by or on behalf of the Department of Health to a health care entity authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health;

(i) Transfers of prescription drugs by or on behalf of the Department of Health to the licensed medical director of a government agency health care entity, authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

(j) Transfers of prescription drugs by or on behalf of the Department of Health to a community pharmacy authorized to purchase prescription drugs, for dispensing to persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

(2) The revocation of a sale or the return of a prescription drug purchased by a hospital or other health care entity, or acquired at a reduced price by or donated to a charitable institution to the manufacturer or the wholesale distributor that sold, donated, or supplied the prescription drug, is not a wholesale distribution prohibited by Section 499.005(21), F.S., provided:

(a) The hospital, health care entity or charitable institution forwards a copy of the documentation for the return to the manufacturer of the product. This documentation must at a minimum comply with the requirements of Rule 61N-1.012, F.A.C.; and

(b) The value of any credit, refund, or exchange for the returned product does not exceed the purchase price or, if a donation, the fair market price of the returned product.

(c) Prescription drugs returned or to be returned to a manufacturer or wholesale distributor must be kept under proper conditions for storage, handling, and shipping as set forth in Section 499.0121, F.S.; and written documentation showing that these conditions were or were not maintained must be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

(3) A person authorized to possess non-dispensed prescription drugs can donate prescription drugs that are not misbranded or adulterated to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs provided the transfer is not for sale or trade and the donor receives no financial benefit (except for tax benefits related to charitable contributions) either directly or indirectly. Records to document the transfer must comply with Section 499.0121(6), F.S., and paragraph 61N-1.008(2)(c), F.A.C.

(4) A person who uses prescription drugs for lawful research, teaching, or testing may obtain a registration number from the department to authorize acquisition of the requisite prescription drugs for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. If applicable, this correspondence should also identify the name in which purchases will be made, the specific prescription drug(s) required for the activity, the quantity which will ordinarily be purchased, the frequency of the purchases, and the name and state permit or license or permit number of suppliers of the prescription drugs. A letter and registration number will be assigned to the person which authorizes the purchase or other acquisition and possession of prescription drugs. This registration number must be included on invoices as required by Section 499.0121(6)(a), F.S.

Rulemaking Authority 499.003(53)(b), 499.012, 499.03, 499.05 FS. Law Implemented 499.003(53)(b), 499.012, 499.03, 499.05 FS. History—New 7-1-96, Formerly 10D-45.0525, Amended 1-26-99, 4-17-01, 1-1-04, 10-4-07, 12-13-09, 6-8-10, Formerly 64F-12.011.

TAB 3. EXECUTIVE DIRECTOR'S REPORT – REGGIE DIXON

1. RETURNS RULE
2. 2012 LEGISLATION AFFECTING DRUGS, DEVICES AND COSMETICS PROGRAM
3. PIS RENEWALS
4. HOSPITALS AND REPACKAGER
5. KUDOS

1. RETURNS RULE

61N-1.012 Records of Drugs, Cosmetics and Devices.

(1)(a) Records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. A complete audit trail includes records which document each transaction or step in the receipt, manufacture, shipping, transfer, or other steps in the channel of trade of that person, whether or not physical possession or handling of the product or component occurs. At a minimum, records shall consist of invoices from the supplier or source which documents acquisition of each product by the person and invoices of sale or other transfer by the person to the recipient. Retail sales transactions to the consumer of over-the-counter drugs, non-restricted devices, or cosmetics are exempt from the requirements of this rule. Additional recordkeeping is required for persons permitted by the department as further stated in this rule.

(b) A person engaged in the distribution of drugs, devices, or cosmetics is not required to maintain documentation from a common carrier that the designated recipient received the product shipped; however, the person must obtain such documentation from the common carrier and make it available to the department upon specific request of the department.

(2) Any person engaged in the manufacture of prescription drugs, the wholesale distribution of prescription drugs, or otherwise receiving or distributing prescription drugs must maintain records as follows:

(a) For each step in the channel of trade, records containing the information required by Section 499.0121(6)(a), F.S., and the Florida permit or license number which authorizes the source to possess and transfer prescription drugs in or into Florida must appear on one document. If delivery of prescription drugs is made to a person other than the purchaser, the name, address or location where the prescription drugs are delivered, and the state license, permit or registration number for that location must be included also.

(b) The state permit or registration number of the purchaser may be omitted if the prescription drugs are exported; but a validated airway bill, bill of lading or other appropriate documentation must be maintained to evidence the exportation of the product.

(c) Invoices must reflect the amount billed per prescription drug product.

(d) Records to document the distribution of prescription drugs required by Section 499.0121(6), F.S., and this rule are to be created during the transaction (i.e., at the time of order, receipt, processing, picking or shipping) and not retroactively created. A pharmacy or other person authorized to possess prescription drugs that transfers prescription drugs to an establishment performing reverse distribution services or destruction activities must prepare or have prepared an inventory or other record of the prescription drugs so transferred prior to the prescription drugs leaving the premises. In addition to the name, address, and license number of the sender and the name, address, and license number of the receiving establishment, the record must include the elements set forth in paragraph 61N-1.023(3)(a), F.A.C.

(e) Inventory. A complete and accurate record of all stock of prescription drugs on hand must be made annually by establishments permitted under Chapter 499, F.S. A physical inventory must be conducted at least annually unless perpetual inventory records are maintained, in which case the physical inventory may be conducted on a biennial basis. Significant inventory discrepancies must be investigated and handled in accordance with written policies and procedures of the establishment. In addition, no later than July 17, 2006, each wholesale distributor shall submit to the department an inventory of drugs it has on hand as of June 30, 2006.

(f) Inventory existing as of June 30, 2006. A wholesale distributor permitted under Section 499.012, F.S., that has purchased a prescription drug on or before close of business June 30, 2006, without the pedigree required by Section 499.01212, F.S., may distribute such drug provided the wholesale distributor submits to the department an inventory of such drugs no later than July 17, 2006, conforming to paragraph (2)(e) above and provided further that such drugs are otherwise in compliance with the provisions of Sections 499.001 through 499.081, F.S. Inventories shall be submitted to the department in written form, email, facsimile, or electronic media excluding a web page. The department will consider the submittal to be a trade secret as defined by Section 812.081(1)(c), F.S., provided that the sending wholesale distributor complies with the requirements of subsections 61N-1.021(1) and (2), F.A.C.

(3) Pedigree Papers.

(a)1. The pedigree papers required by Sections 499.01212, F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the

transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

2. A copy of the pedigree paper must be maintained by each wholesaler distributor preparing a pedigree paper and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesaler distributor preparing the pedigree paper; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesaler distributor serves as the repository of its customer's pedigree, the wholesaler distributor must specify on the customer's invoice or other distribution document the method for immediately accessing all pedigrees associated with each prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.

(b) If a wholesale distributor uses the statement contained in Section 499.01212, F.S., "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer" the wholesale distributor must provide to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group must provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(c) Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," either Form DH 2129 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2129 must be used to comply with the requirement in Section 499.01212, F.S., for the distribution of a prescription drug. Beginning July 1, 2006, a repackager must use either "Prescription (legend) Drug Pedigree – Repackager" Form DH 2135 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2135. A wholesaler distributor that further distributes a repackaged prescription drug must include in the pedigree the information related to the repacked drug contained in Form DH 2135 or the electronic record that contains all the elements of Form DH 2135. These forms may be used prior to July 1, 2006, to comply with the pedigree paper requirements of Section 499.01212, F.S., at the discretion of the wholesaler distributor. An electronic signature may be used on a pedigree paper. An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-Rom or smart card or similar devices. Additional information to that required by forms DH 2129 and DH 2135 may be included on a pedigree provided it does not detract from or confuse the history of the distribution of the drug.

(d) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesaler distributor providing the pedigree paper.

(e) Effective March 1, 2004, a pedigree paper under Section 499.01212, F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record. A prescription drug wholesaler distributor that receives or prepares a pedigree paper under Section 499.01212, F.S., and this chapter that traces the previous distributions of a prescription drug back to a prescription drug wholesaler distributor that is not listed on the department's web site as an authorized distributor of record for the drug's manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesaler distributor is an authorized distributor of record in accordance with the criteria of Section 499.01212, F.S.

(f) Returns.

1. When a distribution of a prescription drug by a wholesaler distributor to an ~~authorized recipient~~ pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that ~~shipment~~ prescription drug by the ~~authorized~~ recipient to the wholesaler distributor need not be reflected in ~~the a~~ pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within ~~seven~~ fourteen calendar days after the date of receipt of the original shipment:

a. The ~~authorized~~ recipient ships the specific unit of the prescription drug back to the wholesaler distributor from which that specific unit was purchased; or

b. The ~~authorized~~ recipient transmits a documented communication to the wholesaler distributor from which the prescription drug was purchased stating the ~~authorized~~ recipient's intent to return the shipment in accordance with the ~~wholesaler's~~ wholesale distributor's prescribed written policies and procedures and the wholesaler distributor communicates authorization for return of the product.

2. Any returns to a wholesaler distributor ~~by an authorized recipient~~ that are not within the scope of subparagraph 1. shall be

reflected in the a pedigree paper ~~trail~~ for any further subsequent wholesale distributions of the returned drug product to the extent required by Section 499.01212, F.S.

3. An ~~authorized~~ recipient that returns a ~~shipment-prescription drug~~ to the wholesaler distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product,

a. That the specific unit (exact unit) being returned was purchased from the receiving wholesaler distributor (including the corresponding sales invoice number and the date of the sale from that wholesaler distributor to the authorized recipient); and

b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.

c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.

(g) For purposes of Section 499.003(31)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization codes.

(h) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesaler distributor consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., (and that wholesaler distributor provides a pedigree to its customer consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., the wholesaler distributor must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesaler distributor provides to its customer.

(i) A wholesaler distributor that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesaler distributor prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (h) above.

(j) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.01212, F.S., to provide a pedigree paper upon distribution of the manufacturer's prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted under Chapter 499, F.S., as a non-resident prescription drug manufacturer based on its relationship with the manufacturer.

(k) Emergency Distributions. A wholesale distributor may distribute and a purchasing pharmacy or health care practitioner authorized by law to purchase prescription drugs may accept a prescription drug for which a pedigree that complies with Section 499.01212, F.S., is not available, when the prescription drug is required immediately to treat a specific patient with a life-threatening medical condition or a medical condition that will result in serious bodily harm. A pharmacist for the purchasing pharmacy, or the health care practitioner, shall supply a statement to the supplying wholesale distributor(s) that the emergency meets this rule paragraph's requirements and the supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug.

(4) Retailers of veterinary legend drugs or medical oxygen must also maintain a prescription or other order of an authorized practitioner evidencing the authority of the purchaser or recipient to receive the veterinary legend drug or medical oxygen. A veterinary legend drug retailer must have the prescription prior to delivery of the drug to the customer. In the case of a medical oxygen retailer, the prescription or order for medical oxygen must be in writing and in the possession of the retailer within 30 days of delivery of the drug to the patient. An order or prescription for veterinary legend drugs or medical oxygen does not constitute authority for the retailer to sell to the purchaser beyond 12 months from the date of the original sale.

(5) A copy of the Florida Drug and Cosmetic Act, Chapter 499, F.S., and Chapter 61N-1, F.A.C., Regulations for Drugs, Devices and Cosmetics, must be at the permitted establishment.

(6)(a) Records for permittees not physically located within the state may be maintained at a central location outside of the state but must be made available for inspection at a permitted establishment or at the department's address within 2 working days after a request for inspection.

(b) Records for permittees located in the state or persons located in Florida and required to be permitted under Chapter 499,

F.S., may be stored by computer or other electronic means at a central location inside or outside of the state, but must be readily available and immediately retrievable, i.e., subject to inspection at the permitted establishment during the inspection.

1. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to Sections 499.001-.081, F.S., in that person's name.

2. If not maintained at a central location, records must be maintained at the permitted location or, if not otherwise permitted, at the address reflected on the product registration.

3. A permitted establishment in Florida that maintains records at a location outside of the state must have a method, such as computerized access, to make records readily available and immediately retrievable. These records must also be made available at the permitted establishment for copying or reproducing within two working days after a request.

4. An establishment permitted at an address outside of the state must make records available for inspection within two working days after a request.

(c) Records for permittees may be copied or reproduced by the department or the Florida Department of Law Enforcement.

(d) If hard copies (originals or true copies) of required records are not maintained at the permitted establishment in Florida, the department or Florida Department of Law Enforcement must be able to review automated records for any and all records required to be maintained under Chapter 499, F.S., without requesting a specific source, recipient, product, date, etc.

(7) Except as provided in Section 499.012(2)(e), F.S., and paragraph (3)(b) of this rule, records of other persons not required to be permitted but subject to regulation under Chapter 499, F.S., must be made available to the department or the Florida Department of Law Enforcement within five business days of the request for inspection, copying, or reproduction.

(8) Records involving drugs, devices, or cosmetics may be maintained by electronic methods, such as computers or imaging devices. Originals or true copies of required records documentation must be maintained by the person involved in the transaction, including brokers and agents. If electronic methods are used to maintain records related to prescription drugs and these methods do not maintain a true copy of the original record, such as the actual image of the original document, then the security system of the permittee must provide protection against tampering with computers or electronic records.

(9) Documentation provided to the department pursuant to an inspection may not be altered or defaced in any manner to obstruct or conceal any required or other information recorded on the document.

(10) All required records must be retained for a period of two years following disposition of the drug, device or cosmetic, or three years after the creation of the records, whichever period is longer; and must be available to the department for such period or as long as records are retained if longer. Records must be retained beyond the retention period if the person has been notified that an investigation or inspection has been initiated by the department and the investigation has not been completed when the mandatory retention period expires.

(11) Manufacturers shall maintain formulas of drugs and cosmetics, including all ingredients, and shall make these available to the department upon request, either during an inspection or by certified mail.

(12) An establishment permitted under Chapter 499, F.S., that shares a facility with another person or business shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other person or business. A person permitted under Chapter 499, F.S., that also conducts other business activities not permitted under Chapter 499, F.S., shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other business activities. For the purpose of this rule, those operational systems required to be kept separate and distinct shall mean all records, inventory, storage areas, repackaging operations, quarantine areas, and manufacturing operations, but this rule shall not require separate entrances to the establishment nor partitioning. A Retail Pharmacy ~~Drug wholesaler~~ Wholesale Distributor however, is not required to maintain its stock of prescription drugs which may be distributed through a wholesale transaction separate from the stock of prescription drugs which may be dispensed by a retail pharmacy.

(13) An establishment permitted to purchase or possess prescription drugs that has no records or has not done any business under the permit that would require such records, shall upon request, provide to the department a written statement to that effect.

(14) The recordkeeping requirements of this subsection do not apply to the prescription dispensing records of a pharmacy or to the patient medical records of a licensed practitioner; however, such records may be required to be produced pursuant to a subpoena issued by the department under Section 499.002(3), F.S.

(15) Charitable Donations of Prescription Drug. A physician or other authorized recipient donating prescription drugs, including prescription drug samples, pursuant to Section 499.003(53)(b)5, F.S., must prepare and maintain a donation record that includes at a minimum:

(a) The donor's name, address, telephone number, the practitioner's state license number, and D.E.A. number if a controlled substance is donated;

(b) The manufacturer, brand name, strength, and dosage form of the product; the quantity donated by lot number; and the expiration date of the product;

(c) The date of the donation;

(d) The name, address, and state license number that authorizes the possession of prescription drugs by the charitable organization, if applicable; and

(e) Within 48 hours of receipt, excluding holidays and weekends, the recipient charitable institution must provide a written receipt to the donor acknowledging receipt of the donated prescription drugs.

(16) Establishing an ongoing relationship pursuant to Sections 499.01212, F.S. A wholesale distributor that is not listed as an authorized distributor of record on the list submitted to the department by a prescription drug manufacturer may request the department add the wholesale distributor to the department's web site of authorized distributors of record for a drug manufacturer for purposes of the pedigree paper requirements of Section 499.01212, F.S., that become effective March 1, 2004, provided that such wholesale distributor satisfies the requirements of paragraph (a) or (b) below.

(a) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S. If the information submitted in subparagraphs 1. and 2. is based on the cumulative activity of an affiliated group, a wholesale distributor or its affiliated group must submit the information in subparagraph 3. below to document the eligibility of the individual wholesaler distributor establishment that is a member of the affiliated group to be an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of \$100 million or more submit either:

a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least \$100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR

b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of \$100 million or more in the most recent fiscal year, OR

c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, of at least \$100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least \$100 million in prescription drug sales, excluding customer returns. AND

2. For each manufacturer for whom the wholesaler distributor claims authorized distributor of record status, submit both subparagraphs a. and b. to document that the wholesaler distributor annually purchases not less than 90%, based on dollar volume, of all of its purchases of a manufacturer's prescription drug products directly from that manufacturer.

a. A computerized listing of all of a manufacturer's prescription drugs purchased by the wholesaler distributor during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, regardless of the source of those prescription drugs. This report must be totaled. AND

b.i. A computerized listing of all purchases of a manufacturer's prescription drugs directly from the manufacturer during the same time period. This report must be totaled. The detail should include the invoice number, invoice date, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least 90% of the wholesaler distributor's purchases of a manufacturer's prescription drug products directly from that manufacturer, excluding returns to the manufacturer. OR

ii. Copies of the manufacturer's sales invoices of prescription drugs to the wholesaler distributor. An adding machine tape, or equivalent, must be included that lists each invoice, in order, and provides a total of all invoices submitted. A statement must be provided that the invoices document at least 90% of the wholesaler distributor's purchases of a manufacturer's prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

3. Each wholesaler distributor establishment that applies to the department to be listed as an authorized distributor of record of a drug manufacturer based upon its affiliated group's ongoing relationship with the manufacturer, or the affiliated group on behalf of each wholesaler distributor establishment, must submit the names and address of all member wholesaler distributor establishments of the affiliated group. In addition, each wholesaler distributor establishment must either:

a. Conduct its prescription drug wholesale activities under an establishment name that incorporates the same business name as

the affiliated group upon which the eligibility criteria for the affiliated group was met, or

b. Hold a valid prescription drug wholesaler distributor permit or out-of-state prescription drug wholesaler distributor permit issued under Chapter 499, F.S.

(b) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of \$100 million or more submit either:

a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least \$100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR

b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of \$100 million or more in the most recent fiscal year, OR

c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month period based on the most recent calendar quarter, of at least \$100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least \$100 million in prescription drug sales, excluding customer returns.

2. For each manufacturer for whom the wholesaler distributor claims authorized distributor of record status, submit a., b., or c. to document that the wholesaler distributor has a verifiable account number issued by the manufacturer and has made at least 12 purchases of prescription drugs directly from that manufacturer using the verifiable account number.

a. If the wholesaler distributor is a member of an affiliated group and all purchases from that manufacturer are made at a central location for the wholesaler distributor, copies of at least 12 invoices dated during the previous 12 months from the date the information is submitted, which invoices document purchases of prescription drugs, at least one unit of which on each invoice was not returned, under that central account number but shipped to the wholesaler distributor's address for whom the authorized distributor of record status is claimed. A statement must be provided that the invoices document purchases of prescription drugs for the wholesaler distributor for whom the authorized distributor of record status is claimed and that the wholesaler distributor did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

b. If the wholesaler distributor is a member of an affiliated group and all purchases from that manufacturer are made at a central location and received at a central location for the wholesaler distributor, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account number which is clearly assigned to the wholesaler distributor at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that central location and that the central location or wholesaler distributor for which the drugs were obtained did not return to the manufacturer at least one unit of the prescription drugs on each invoice, and that the central location shipped at least 12 times to the individual wholesaler distributor for whom the authorized distributor of record status is claimed during the 12 months based on the fiscal year or designated timeframe.

c. For all other wholesale distributors, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account number that is clearly assigned to the wholesaler distributor at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that wholesaler distributor and that the wholesaler distributor did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

Rulemaking Authority 499.003, 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS. History—New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06, Formerly 64F-12.012.

2. 2012 LEGISLATION

2012 Legislation Affecting Drugs, Devices, and Cosmetics Program

Bill	Summary
<p>SB 364</p> <p>2012-37</p> <p>July 1, 2012</p>	<ul style="list-style-type: none"> • Creates new “Restricted Rx Drug Distributor – Blood Establishment” permit that allows blood establishments, that also qualify as health care entities, to purchase, possess, and distribute certain prescription drugs, including drugs essential to services performed or provided by blood establishments, to health care establishments and closed pharmacies so long as those drugs are related to the services provided by the blood establishment. <ul style="list-style-type: none"> ○ Empowers DBPR to promulgate rules to setting out the specific prescription drugs that the new permit type would be allowed to distribute. ○ Allows Restricted Prescription Drug Distributor – Blood Establishment permit holders to purchase, possess and distribute prescription drugs without having to be licensed as Health Care Clinic Establishments. • Exempts blood establishments that manufacture blood and blood components intended for transfusion from the requirement to be permitted as a prescription drug manufacturer and to register the products they manufacture. • Clarifies that restricted prescription drug distributor permits are limited to entities located in Florida that conduct distributions that are not wholesale distributions.
<p>HB 517</p> <p>2012-61</p> <p>July 1, 2012</p>	<ul style="list-style-type: none"> • Revises following definitions: <ul style="list-style-type: none"> ○ “Distribution” to clarify that billing and invoicing activities, and the records associated therewith, are not actually distributions, but rather evidence of distribution transactions, thus payment processing centers that provide services for wholesalers are not required to be licensed. ○ “Drug” & “Prescription Drug” to clarify that active pharmaceutical ingredients are drugs, and in some instances, prescription drugs, depending on the final dosage form of the drug. ○ “Drug” to clarify that the “drug” components of medical devices are clearly drugs within the scope of the department regulation. ○ “Establishment” to clarify that for licensing purposes, an establishment, may include multiple contiguous buildings, floors, suites, etc. • Removes the requirement that licensees participating in the 340 B special pricing program maintain a separate physical inventory for the prescription

drugs purchased and distributed under the program.

- Creates the following new exemptions from licensure:
 - a. Drug establishments, physically located in the United States, do not need a license to distribute active pharmaceutical ingredients to Florida licensed prescription drug manufacturers for the manufacturing of finished prescription drug products under the following conditions:
 - The product is the subject of an approved “New Drug Approval, Abbreviated New Drug Approval, New Animal Drug Approval, or Therapeutic Biologic Application”.
 - The application, active pharmaceutical ingredient or finished dosage form has not been withdrawn or removed from the U.S. market for public health reasons.
 - b. Drug establishments, physically located in the United States, do not need a license to distribute limited amounts of non-repackaged prescription drugs, to a Florida licensed prescription drug manufacturer (or the holder of a DDC issued exemption letter) for research and development.
 - The drugs must be labeled: “Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale.”
 - The Florida prescription drug manufacturer must ensure that the product is not resold or used, directly or indirectly, on humans, except for lawful clinical trials and biostudies.
 - c. Restricted prescription drug distributors that qualify as health care entities do not need a repackager license to repackage prescription drugs in Florida for its their own use or for distribution to hospitals or other health care entities in the state for their own use, as long as the distributor:
 - Notifies DBPR, in writing, 30 days in advance;
 - Is under common control with the hospital or health care entities they distribute prescription drugs;
 - Repackages in accordance with state and federal current good manufacturing standards; and
 - Labels the repackaged drugs according to state and federal law.

Note: Under this exemption, the restricted drug distributor is exempted from the requirement to register the repackaged prescription drugs products with the department.
- Requires those entities engaging in distribution pursuant to the newly created

	<p>exemptions to create and maintain certain records and to make those records available to the department within 48 hours of a request from the department, regardless of the location of the records.</p> <ul style="list-style-type: none"> • Requires Florida resident manufacturers that are the recipients of prescription drugs from an exempt entity to notify the department within 14 days of the receipt of misbranded or adulterated product, or of product that does not meet federal good manufacturing standards.
<p>HB 5511</p> <p>2012 - 143</p> <p>July 1, 2012</p>	<p>Creates the Division of Drugs, Devices, and Cosmetics within the Department of Business and Professional Regulation [s. 20.165(2)(d), F.S.]</p> <p>Deletes the DDC Trust Fund and transfers funding of the Division of Drugs, Devices, and Cosmetics within the Professions Regulatory Trust Fund [effective November 1, 2012]</p> <p>Cleans up references in Chapter 499, F.S., to the "Surgeon General" and the "Department of Health" to appropriately reflect the "Secretary of Business and Professional Regulation" and "Department of Business and Professional Regulation."</p>
<p>HB 1089</p> <p>Upon Becoming Law</p>	<p>Exempts the personal information (home address, telephone number, & photographs) of current and former DBPR investigators and inspectors (and their spouse and children and schools, day care centers, etc.) from being disclosed pursuant to public records, provided the inspector or investigator has made reasonable efforts to protect such information from being accessible through other means available to the public.</p>

3. PIS RENEWALS

4. HOSPITALS AND REPACKAGER

5. KUDOS

Florida Department of Business & Professional Regulation

License efficiently. Regulate fairly.

HOME

Alcoholic Beverages & Tobacco

Boxing Commission

Certified Public Accounting

Condominiums, Timeshares &
Mobile Homes

Drugs, Devices and Cosmetics

Hotels and Restaurants

Parl-Mutuel Wagering

Professions

Real Estate

Regulation

Secretary's Office

- Administration
- Budget and Finance
- Communications
- General Counsel
- Inspector General
- Legislative Affairs
- Service Operations
- Technology

Kudos

Kudos to DBPR Employees

DBPR employees get compliments from our customers every month. These compliments come to the Office of Communications via the Web site, where customers can choose to compliment a DBPR employee.

How to Submit a Kudos

To submit a kudos for a DBPR employee, please e-mail your submission to IntheLoop@dbpr.state.fl.us using the format provided below. We love hearing how our fellow employees are helping customers in the customer own voice.

Name:

Employee Name(s):

Employee Division:

Date:

Details:

* Submissions that are not in the above format will no longer be displayed.

Name: Jay Howard

Employee Name(s): Tim Nungesser, Matilde Miller, Jessica Crawford, Ruth Dillard, Lynn Smith, Larry Hurley, Reggie Dixon

Date: 2012 Legislative Session

Details: I am the new Analyst in the Senate responsible for reviewing your budget and legislation. Being new to your budget this year, I had to rely heavily on your staff for assistance. Everyone was amazing and I could not have made it through Session without their help.

Your Legislative Team of Tim Nungesser, Matilde Miller, and Jessica Crawford were exceptional. I had to call for quick fiscal analysis reviews along with late night phone calls and meetings and everyone was very patient with me and always willing to help in anyway they could.

I enjoyed meeting Ruth Dillard and the budget team this year and they were also very helpful. A special thanks to Lynn Smith for being my point of contact for most of my requests. If she was not able to help me right away, she had someone get with me very timely to help with my requests.

Also, Larry Hurley was especially helpful when it came to revenue analysis questions.

Also, a special thanks to Reggie Dixon and his staff at the DDC. There were a lot of issues with their program and they went above and beyond assisting me when needed including attending several committee meetings in case the members had questions.

I have not named everyone that helped me this year but I just wanted to let you know I think you have a wonderful staff and I am so thankful for their assistance this 2012 Session.

I promise to be a lot better prepared for next Session but it is nice to know there is a great staff at DBPR to assist me anytime I need them.

Name: Eric Phillips

Employee Name(s): Natasha Lafaille

Employee Division: DDC

Date: 3/21/2012

Details: Natasha is an excellent employee and always willing to assist us here at PSS. Kudos to Natasha for providing great customer care!

Name: Michael Wiggs

Employee Name(s): Dinah Skrnich

Employee Division: Drugs, Devices and Cosmetics Program

Date: 3/28/12

Details: I would like to thank Ms. Skrnich for their rapid response to our request for an amendment form. During our phone call, Ms. Skrnich was well informed and provided a thorough walkthrough of the steps needed to proceed. After I provided the information, the departments response was incredibly rapid. Thanks again for great "customer service".

Name: Michael Wiggs

Employee Name(s): **Dinah Skrnich**

Employee Division: Drugs, Devices and Cosmetics Program

Date: 3/28/12

Details: I would like to thank Ms. Skrnich for their rapid response to our request for an amendment form. During our phone call, Ms. Skrnich was well informed and provided a thorough walkthrough of the steps needed to proceed. After I provided the information, the departments response was incredibly rapid. Thanks again for great "customer service".

Name: mary korda

Employee Name(s): **Charles McCurdy**

Employee Division: customer contact center

Date: mar 29, 2012

Details: Charles was very helpful in answering a myriad of questions, peculiar to my condominium association, regarding annual filings. When I could not access the website (probably due to high activity), Charles gave me exact instructions as to finding the webpages I needed. He was clear and accurate. He was POLITE and PATIENT. I am in no way related to this man. My purpose is simply to give him a positive mark on his work record.

Name: Anthanette Ford-Paul, Real Estate Broker, Ford-Paul Realty

Employee Name(s): **Charles McCrudy**

Employee Division: Real Estate License

Date: April 2, 2012

Details: After speaking on the phone with someone name Carla, who was rude and unhelpful and upon having to call back because I could not communicate with her, Mr Charles McCrudy answered the phone and was very helpful and very professional. He answered my questions with experience and efficiency. He was able to calm me down as a customer because I was very angry after talking with Carla, who did not answer any of my questions, she just wanted her's answered, it was a one-sided conversation going no where, I was aggravated. However, Mr McCrudy did answer my questions with knowledge and politeness and I appreciated that. He made me feel like my dollars were being well spent with DPBR. Thank you for hiring him, he's great!

Name: Marjorie Boyd

Employee Name(s): **Olvie Demosthene**

Employee Division: Division of Regulation

Date: 3/20/12

Details: I wanted to take the time to compliment Ms.Olvie Demosthene. She was very polite and professional when she visited our animal shelter for our inspection. I hope we get to see her again in the future. Keep up the great work Ms. Olvie.

NAME: Allison Nyles, Owner of Scrambles Café in Ocala

EMPLOYEE NAME: **Ben Bryant – Jacksonville, District 5**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 3-19-2012

DETAILS: Allison Nyles of Scramble's Café in Ocala wanted to let us know that you are very thorough and hard but fair. The job you do and the time you take to explain things helps them to improve and run their restaurant better.

NAME: Terry Nischam, Owner of Seaside Dawgs & Beef

EMPLOYEE NAME: **Paulina Brewer – Tallahassee, Office of Plan Review**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 3-21-2012

DETAILS: Thank you soooo much, I'm actually crying! Tears of joy! It has been a tedious process, not DBPR, actually, this was the most user friendly process of all. Can't wait to meet our inspector and get our process underway. Will she actually be giving us the go ahead to open or not? Again, thank you Paulina! You've made our day.

NAME: Angeia Bartolone, Forum Publishing Group

Skrnich, Dinah

From: Dixon, Reggie
Sent: Thursday, May 03, 2012 11:49 AM
To: Lawson, Ken
Cc: Walker, Michael; Burnett, Rebecca; Jernigan, Robert; Porter, Trisha
Subject: FW: Merck Sharp & Dohme Corp. Change of Ownership Applications

Mr. Secretary,

Just wanted to take another opportunity to share words of appreciation received regarding the DDC employees Trish Porter and Robert Jernigan from one of our licensees. We are fortunate to have these folks.

Reggie

Reginald D. Dixon
Executive Director

From: Jernigan, Robert
Sent: Thursday, May 03, 2012 11:44 AM
To: Dixon, Reggie; Burnett, Rebecca
Cc: Porter, Trisha
Subject: FW: Merck Sharp & Dohme Corp. Change of Ownership Applications

FYI the email below. Kind words about Trisha.

Robert F. Jernigan
Chief of Compliance & Enforcement
Drugs, Devices & Cosmetics Program
Department of Business and Professional Regulation
1940 North Monroe Street, Suite 26A
Tallahassee, Florida 32399-1047
850-717-1816 - Telephone
850-414-8240 - Facsimile

From: Crump, Wendy [mailto:wendy_crump@merck.com]
Sent: Thursday, May 03, 2012 10:03 AM
To: Jernigan, Robert
Cc: Hansen, Craig M; Porter, Trisha; Loprete, Jeffrey
Subject: Merck Sharp & Dohme Corp. Change of Ownership Applications

Dear Mr. Jernigan:

We would like to express our sincere thanks to you and the staff of Florida's Department of Business and Professional Regulation. Merck Sharp & Dohme Corp. change of ownership took place on 01 May. We have received our resident state license, and the legal documentation for the change of ownership. Merck's resident state license and legal documentation for the change of ownership were submitted via e-mail, and next day today to Florida's DBPR.

We greatly appreciate all your guidance, support, and patience.

Thank you.

Sincerely,

5/8/2012

Wendy

dy
16, 2012 11:22 AM
art'
M; Loprete, Jeffrey; Greziak, Charles R.
Sharp & Dohme Corp. Change of Ownership Applications

Dear Mr. Jernigan:

Merck Sharp & Dohme Corp., Legal Entity Integration is on schedule to occur on 01 May, 2012.

Merck's applications and file identification numbers are:

Applicant ID No.: 11408 (Complimentary Drug Distributor)
Permit No.: 40

Applicant ID No.: 4585 (Out-of-State Prescription Drug Wholesale Distributor)
Permit No.: 23

Applicant ID No.: 4483 (Renewal Out-of-State Prescription Drug Wholesale Distributor)
Permit No.: 23:2345

Application ID No.: 6748 (Out-of-State Prescription Drug Manufacturer)
Permit No.: 26

We have provided responses and documentation to all the deficiencies, except for the new resident state permit, and the legal documentation for the change of ownership.

Merck's new resident state permit applications were submitted to the resident state regulatory department. The new resident permit will not be issued before the actual change of ownership which is 01 May. Also, the legal documentation for the change of ownership will be issued on 01 May.

We keep you informed of the status of the pending documents, and will submit the pending documents via e-mail and overnight mail upon receipt to the Regulatory Specialist.

Thank you for all your assistance and guidance.

Best Regards,

Wendy

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5/8/2012

for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

Skrnich, Dinah

From: Dixon, Reggie
Sent: Monday, March 05, 2012 12:29 PM
To: Lawson, Ken
Cc: Walker, Michael; Jernigan, Robert; Burnett, Rebecca; Porter, Trisha; Grayson, Mary
Subject: FW: Response for Axogen Corporation

Mr. Secretary,

I just wanted to take a moment to brag on a couple of DDC employees, Trisha Porter and Mary Grayson. The summary from Robert provides the background. These two employees really represent the department well. Thanks.

Reggie

Reginald D. Dixon
Executive Director

From: Jernigan, Robert
Sent: Monday, March 05, 2012 11:05 AM
To: Burnett, Rebecca; Dixon, Reggie
Cc: Grayson, Mary; Porter, Trisha
Subject: RE: Response for Axogen Corporation

Reggie/Rebecca,

Just wanted to make sure that you saw the appreciation expressed below, 99% of which is due to Trisha's and Mary's efforts—not mine.

By way of background, this company is located in Florida and manufactures/distributes non-drug Rx devices, and is trying to get a license to market the device in California. In an attempt to assist the company in getting the California license, we confirmed that Florida law does not require a license for distributing such products or a manufacturer's permit for FDA-approved devices. The California Board of Pharmacy, however, requires the company to have a domestic state license—regardless of whether underlying state law requires it. So the company applied for and received a Rx Drug Wholesale Distributor permit.

Thanks,

RJ

Robert F. Jernigan
Chief of Compliance & Enforcement
Drugs, Devices & Cosmetics Program
Department of Business and Professional Regulation
1940 North Monroe Street, Suite 26A
Tallahassee, Florida 32399-1047
850-717-1816 - Telephone
850-414-8240 - Facsimile

5/8/2012

From: Mark Friedman [mailto:mfriedman@axogeninc.com]
Sent: Monday, March 05, 2012 10:04 AM
To: Porter, Trisha
Cc: Grayson, Mary; Jernigan, Robert
Subject: RE: Response for Axogen Corporation

Trisha, Mary and Robert,

Thank you for your assistance through this cumbersome and difficult process with California.

Mark Friedman
AxoGen, Inc.
(386) 462-6820 Direct Dial

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From: Porter, Trisha [mailto:Trisha.Porter@dbpr.state.fl.us]
Sent: Monday, March 05, 2012 9:58 AM
To: 'Debbie.Anderson@dca.ca.gov'
Cc: Mark Friedman; Grayson, Mary
Subject: Response for Axogen Corporation

Ms. Anderson:

Attached is a license verification form that we provide for our state and a response regarding your question for Axogen Corporation with permit 22:20199, here is your response.

She wants an answer to the following question from California's form 17M-17

"Has the licensee been found guilty of any violation for which disciplinary action was taken? Yes or No If disciplinary action has been taken against the licensee, please provide this office with all the available documentation regarding the action?"

No they have no pending or past disciplinary violations, this can be verified at:

<https://www.myfloridalicense.com/wl11.asp?mode=2&search=Name&SID=&brd=&typ=>

Thanks.

Trisha S. Porter

Regulatory Specialist II
Drug, Devices & Cosmetics Program
1940 North Monroe Street, Suite 26A+
Tallahassee, Florida 32399-1047
(850) 717-1817 My Direct Number
(850) 717-1800 Main Telephone Number
www.myfloridalicense.com/dbpr

5/8/2012

Skrnich, Dinah

From: Dixon, Reggie
Sent: Thursday, January 26, 2012 1:56 PM
To: Lawson, Ken
Cc: Walker, Michael; Burnett, Rebecca; Grayson, Mary; Lafaille, Natasha; Porter, Trisha
Subject: FW: Thank you card

Attachments: DOC012612.pdf



DOC012612.pdf (7
KB)

Mr. Secretary,

I would like to take a minute to brag on the members of our DDC licensing unit. This unit processes all the applications received by the program. The attached card came in today. This unit is a well-oiled machine. The processors work tirelessly to ensure that the applications are timely processed. They also receive and respond to the majority of the calls forwarded to the DDC unit from the CCC. These folks have been doing an exceptional job.

Reggie

Reginald D. Dixon
Executive Director

-----Original Message-----

From: Burnett, Rebecca
Sent: Thursday, January 26, 2012 1:11 PM
To: Dixon, Reggie
Subject: Thank you card

-----Original Message-----

From: ddc.scanner@dbpr.state.fl.us [mailto:ddc.scanner@dbpr.state.fl.us]
Sent: Thursday, January 26, 2012 6:43 PM
To: Burnett, Rebecca
Subject: Send data from MFP07335445 01/26/2012 15:42

Scanned from MFP07335445

Date: 01/26/2012 15:42
Pages: 1
Resolution: 200x200 DPI

Trisha, Mary and Natasha

Thanks for your help &
patience on our files. From
the Pharmalicense Team.

Dawn Dee, Pharmalicense

Skrnich, Dinah

From: Dixon, Reggie
Sent: Thursday, December 08, 2011 1:25 PM
To: Lawson, Ken
Cc: Walker, Michael; Skrnich, Dinah
Subject: FW: Exemption Letter

Mr. Secretary,

I wanted to share with you a positive comment that we received from one of our constituents. Dinah has been with the program for several years and is an asset to both the program and the department. She definitely keeps me pointed in the right direction. Dinah, thanks for all that you do.

Reggie

Reginald D. Dixon
Executive Director

From: Chris Peterson [mailto:chris@herrellplumbing.com]
Sent: Tuesday, December 06, 2011 3:35 PM
To: Dixon, Reggie
Subject: Exemption Letter

Reggie,

This is to let you know that your representative, Dinah Skrnich, was a pleasure to deal with. She was helpful, prompt and professional.

Sincerely,

Chris Peterson
Herrell Plumbing, Inc.

Skrnich, Dinah

From: Dixon, Reggie
Sent: Friday, October 14, 2011 4:26 PM
To: Lawson, Ken
Cc: Walker, Michael; Burnett, Rebecca; Lafaille, Natasha
Subject: FW: Kudos

Secretary Lawson,

Just another example of the fine employees within the DDC program:-)

Reggie

Reginald D. Dixon
Executive Director
-----Original Message-----
From: Communications, DBPR
Sent: Friday, October 14, 2011 4:20 PM
To: Dixon, Reggie
Subject: FW: Kudos

Please see the employee kudos below. Also, please share this with the employee as it will appear in the next In the Loop.

Thanks!

Beth Frady, Deputy Communications Director Department of Business and Professional Regulation 1940 North Monroe St.
Tallahassee, FL 32399-2208
Office: 850.922.8981
Cell: 850.491.0040

NOTE: Most written communications to or from state officials are available to the public upon request. Your email communication may be subject to public disclosure.

-----Original Message-----
From: kudos@dbpr.state.fl.us [mailto:kudos@dbpr.state.fl.us]
Sent: Friday, October 14, 2011 9:16 AM
To: Communications, DBPR
Subject: Kudos

Name: Barbara Bate
Phone:
Email: Barbara.Bate@Airliquide.com
Employee Name(s): Natasha LaFaille
Employee Division: Drugs, Devices and Cosmetics Program
Date: 10-14-11
Details: Natasha followed up to obtain a W9 for me. She has been very courteous and helpful over the several months I have worked with her.

Florida Department of Business & Professional Regulation

License efficiently. Regulate fairly.

HOME

Alcoholic Beverages & Tobacco

Boxing Commission

Certified Public Accounting

Condominiums, Timeshares &
Mobile Homes

Drugs, Devices and Cosmetics

Hotels and Restaurants

Pari-Mutuel Wagering

Professions

Real Estate

Regulation

Secretary's Office

- Administration
- Budget and Finance
- Communications
- General Counsel
- Inspector General
- Legislative Affairs
- Service Operations
- Technology

Kudos

Kudos to DBPR Employees

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Name:

Employee Name(s):

Employee Division:

Date:

Details:

*** Submissions that are not in the above format will no longer be displayed.**

Name: Susan Monahan

Employee Name(s): **Natasha LaFaille**

Employee Division: DBPR - Drugs, Devices & Cosmetics

Date: 1/27/12

Details: I was referred to Ms. LaFaille with a question on a name change to a license. She responded in a timely manner with the information I needed. Thank you.

Name: Susan Lannan

Employee Name(s): **Natasha LaFaille**

Employee Division: Drugs Devices and Cosmetics

Date: January 30 & 31, 2012

Details: Natasha was very helpful to me in getting our compressed medical gas renewals coming to the correct corporate address. Anytime I email Natasha with questions, she is always helpful. If she cannot answer the question, she forwards it to the person that can. She never indicates that it isn't her job or any of the usual comments that some folks will give. She is a true team player. You are lucky to have her.

Name: Bob DeChello

Employee Name(s): **Dinah Skrnich, CPM**

Employee Division: Controlled Substance Reporting Drugs, Devices and Cosmetics Program

Date: 1/31/2012 - 2/1/2012

Details: Dinah was very helpful and her response time exceeded expectations.

Name: Connie Tiburzi

Employee Name: **Peter Newman**

Employee Division: Regulation

Date: January 26, 2012

Details: I hope this email finds you well. I wanted to thank you again for helping me with the skylight issue I had ... a while back. Every time I look up at my skylights, I am grateful for how quickly you stepped in and held them accountable. You and the City of Coral Springs building department saved me attorneys fees, time, and aggravation.

Name: Cindy Brue

Employee Name(s): **Olivia Demosthene**

Employee Division: Regulation

Date: 2-1-2012

Details: I met Olvie today at my office during an inspection. I was nervous because it was my first one and she put me at ease and was very professional at the same time. She helped me to see what I needed to change and treated me with respect. I appreciate the way you handle your business there and hope all your employees are as hardworking and professional as Olvie. Thank you-Sincerely, Cindy Brue LMT

Name: Laney Duval

Employee Name(s): **Carolyn**

Employee Division: Call Center

Date: 2/2/2012

Details: I called from the Clerk of the Circuit Court in Sarasota County at 5 p.m. This lovely young lady was kind enough to go above and beyond in helping to obtain the information that I needed for the person, of whom I was seeking. Although I could not get through to that person, she gave me information that will be helpful in the morning when I call. She was so gracious even when I was very persistent and prodded for more information. Please send her a thank you for me. All agencies need someone like her working their phones.

Name: Richard Watkins

Employee Name(s): **Dinah Skrnich**

Employee Division: Drugs, Devices, and Cosmetics Program

Date: 2-3-2012

Details: Dinah was very helpful and gave prompt attention to our needs. Thank you so much!

Name: Brian Lemay, MS-HCA

Employee Name(s): **Natasha Lafaille**

Employee Division: Department of Business and Professional Regulations

Date: 2/6/12

Details: I would like to express my sincere thanks for the EXCELLENT service and response to questions sent to the Department of Business and Professional Regulations. I would like to recognize and thank Natasha Lafaille with the department of Drugs, Devices and Cosmetics for providing me information to many questions relating to the HCCE requirement.

As you know, most of the time all you receive is complains - but I am very impressed with the Natasha and the Drugs, Device and Cosmetics division for doing an outstanding job!

Name: David Wilpon

Employee Name(s): **Natasha Lafaille**

Employee Division: Drugs, Devices and Cosmetics

Date: 02/07/2012

Details: I just wanted you to know today I had dealings with Natasha Lafaille both on the phone and via email. She was very helpful, courteous and friendly. Not only that but she got me the information I request in a very timely manner. These are very unusual but highly appreciated qualities when dealing with government employees. I wish all personnel I deal with was more like her.

Name: Caren Jones

Employee Name(s): **Natasha Lafaille**

Employee Division: Drugs, Devices and Cosmetics

Date: 2/8/2012

Details: Natasha was very helpful.

NAME: Manager of I-Hop on International Drive

EMPLOYEE NAME: **Machelle Speights (District 4 - Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-25-2012

DETAILS: The manager of the I-Hop on International Drive contacted our office and wanted to thank you. He said you always

professional and helpful. You are an outstanding teacher.

NAME: Manager of Jerkies & Juice

EMPLOYEE NAME: **Kathryn Mantl (District 4 – Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-25-2012

DETAILS: The manager of Jerkies & Juice contacted our office to relay his thanks to you for your assistance during their inspections. He stated that while they have some problems, you explain how they can take care of them. You are always professional and helpful.

NAME: Operator of Lucky Leprechaun

EMPLOYEE NAME: **Savitri Bachoo (District 4 – Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-25-2012

DETAILS: Customer Bill of Rights Feedback... You are receiving this recognition because the operator of the Lucky Leprechaun wanted to commend you. He stated they just had their inspection, and you are doing an excellent job. You are a wonderful person doing a wonderful job fairly and politely. He is more than happy with you!

NAME: Ms. Spellman with La Quinta Inn and Suites

EMPLOYEE NAME: **Sandra Hopper (District 4 – Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-25-2012

DETAILS: Ms. Spellman with La Quinta Inn and Suites contacted our office to say you were wonderful, patient and very educational during your recent visit. You did a great job, and she really appreciates it!

NAME: Laudia A. Jefferson, Hot Diggity Dog Diggity

EMPLOYEE NAME: **Karla Shaffer (District 4 – Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-26-2012

DETAILS: I had my inspection 1/13/12 Carla Shaffer was the inspector that day I am sending a thank-you for Carla's outstanding work performance. She was very professional helped me understand all that my responsibilities would be on my new Venture out in the workplace. I hope Carla will continue to inspect me through the months ahead I hope she at least gets a pat on the back for a job well done Thanks Carla and Happy New Year to you all .

NAME: Ms. Patty Miranda, Operator of Olympic Flame Diner

EMPLOYEE NAME: **Tara Palmer (District 2 – Margate)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-30-2012

DETAILS: Ms. Patty Miranda, Operator of Olympic Flame Diner, contacted our H&R Hotline today. She had the pleasure to get to know you over the past few years. She thinks that you are a great inspector who strives to work with them to make them better. She appreciates you motivating them into getting them where they need to be. You certainly impressed this operator.

NAME: Eric Castellanos, CEO of Latin Café 2000

EMPLOYEE NAME: **Douglas Morgandanes and Reggie Gracia (District 1 – Miami)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-31-2012

DETAILS: I wanted to thank you and your team personally on getting my health department license so efficiently. We have been trying to open the casino and the casino cafe for a while now and Douglas Morgandanes has been a great help on expediting this all for us to get us open as quick as possible. As a business owner I appreciate all the help Douglas gave us and

now we are open and able to employ almost 40 people and serve food to all customers in the casino. The Inspector Mr. Morgadanes sent to us, Reginald Gracia, was also great and very thorough and look forward to seeing him in the follow up inspections. Thanks to Douglas hard work, we are doing well and very grateful to him and his team.

NAME: Maurice from Chatham's Place Restaurant

EMPLOYEE NAME: **Savitri Bachoo (District 4 - Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-31-2012

DETAILS: Maurice from Chatham's Place Restaurant contacted our office to compliment you. He stated you are very reasonable, helpful and always give them tips on how to correct their mistakes.

NAME: Mr. Stewart Reben

EMPLOYEE NAME: **Terrence Diehl (District 2 - Margate)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 1-31-2012

DETAILS: Mr. Reben complimented your performance as an inspector. He felt that you do a great job in conducting thorough inspections.

NAME: Manager of Flipper's Pizzeria

EMPLOYEE NAME: **Savitri Bachoo (District 4 - Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-3-2012

DETAILS: The manager of Flipper's Pizzeria contacted our office to let us know that you conducted the last inspection in a very professional manner. The inspection was relatively quick and thorough, and you explained every item that was cited.

NAME: George Paul with Classic Creations Catering

EMPLOYEE NAME: **Dennis Watson (District 4 - Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-3-2012

DETAILS: George Paul with Classic Creations Catering wanted to let us know that you are doing a great job. You are respectful and helpful. It is a pleasure to have you come in because Mr. Paul knows that you are there to help him, and he really appreciates it!

NAME: Michael Liquoir of Pizzeria Valdano

EMPLOYEE NAME: **Dennis Watson (District 4 - Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-3-2012

DETAILS: Michael Liquoir of Pizzeria Valdano stated that you are doing a great job. He has been in the business for 42 years, and you are one of the best inspectors he has ever had. You are very professional, and help him understand not only what improvements need to be made, but also how to go about doing so.

NAME: Phillip Larrisee from the Marriott Lakeshore Reserve

EMPLOYEE NAME: **Sandra (Sam) Hopper (District 4 - Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-3-2012

DETAILS: Phillip Larrisee from the Marriott Lakeshore Reserve called to compliment you. He only had praises for you. He stated you are an outstanding inspector, absolutely one of the greatest! You are easy to work with, very informative and understanding. You provided all the details that they needed. He appreciates everything you did for them, and stated "you are a credit to the department!"

NAME: Harrison Wheeler, The GEO Group

EMPLOYEE NAME: **Landon Lang – Plan Review**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-6-2012

DETAILS: This e-mail is being sent with respect to the licensing process my company, The GEO Group, went through this past November and December, 2011.

Mr. Landon Lang of the DBPR assisted me in the process of licensing the Park Place Café®, and he could not have been more agreeable or accommodating. I was very pleased in all respects with the service he provided, as well as with his wonderful attitude, and I heartily commend him to his supervisors.

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Florida Department of Business & Professional Regulation

License efficiently. Regulate fairly.

HOME

Alcoholic Beverages & Tobacco

Boxing Commission

Certified Public Accounting

Condominiums, Timeshares &
Mobile Homes

Drugs, Devices and Cosmetics

Hotels and Restaurants

Pari-Mutuel Wagering

Professions

Real Estate

Regulation

Secretary's Office

- Administration
- Budget and Finance
- Communications
- General Counsel
- Inspector General
- Legislative Affairs
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Name:

Employee Name(s):

Employee Division:

Date:

Details:

* Submissions that are not in the above format will no longer be displayed.

Name: Richard Mette, State Attorney's Office 4th Judicial Circuit

Employee: **Barbara Jackson**

Employee Division: Regulation-Jacksonville

Date 2/22/12

Details: Ms. Jackson is one of the most professional and courteous individuals I have ever spoken to when I call the Jacksonville office. I call many local and state government offices and she is always responsive, courteous and a pleasure to speak to. What a wonderful employee.

Name: Barbara Hilliard

Employee Name(s): **Barbara Smith**

Employee Division: Regulatory Specialist II

Date: Feb & March 2012

Details: I just want to thank you for having a person like Barbara Smith working there. She helped me out in so many ways. She never gave up on me and she gave me the exact instructions on how to obtain my license and in a motherly way too. I appreciate that so much and I think they should all be like her. God Bless you all.

Name: Dr.Manuel

Employee Name(s): **Natasha Lafaille**

Employee Division: Drugs, Devices and Cosmetics

Date: 02/17/12

Details: The service of this Department is very efficiency and fast. We are very satisfied.

Customer Name: J. Roland Hayden, President, Pritchard Sports & Entertainment Group

Employee Name: **Elizabeth Kress**

Employee Division: Pari-Mutuel Wagering

Date: February 3, 2012

Details: We deal with state agencies throughout the country. I can honestly say we have never received such immediate service as you have provided today. The rest of the country could learn a good lesson from the state of Florida. Thank you so much for your prompt response.

NAME: William Norris, Manager of Shavedway Subs

EMPLOYEE NAME: **Terrence Diehl (District 2 - Margate)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-9-2012

DETAILS: William Norris, Manager of Shavedway Subs said he was very impressed with your knowledge and professionalism. He stated that even though he received an administrative complaint, he was satisfied as it was legitimate. Mr. Norris said Inspector Diehl has helped him improved his business and increase his understanding of the food service industry over the years, and he

was truly thankful for having such a great inspector.

NAME: Manager of Pei Wei in Kissimmee

EMPLOYEE NAME: **Sandra (Sam) Hopper (District 4 – Orlando)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-15-2012

DETAILS: The manager of Pei Wei in Kissimmee called to relay his thanks regarding your recent inspection. He stated you were very professional throughout the inspection, and that your visit was very educational.

NAME: Customer – Mr. Anthony Garcia

EMPLOYEE NAME: **Erick Charpentier and Mark Cannella (District 3 – Tampa)**

EMPLOYEE DIVISION: Hotels and Restaurants

DATE: 2-21-2012

DETAILS: Mark was awesome and very knowledgeable and contacted him in a timely manner regarding his complaint; Mr. Garcia stated that he was very impressed with his quick response. He also said that Erick Charpentier was great and knowledgeable

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Skrnich, Dinah

From: Bryan, Ronda
Sent: Friday, January 13, 2012 8:10 AM
To: Skrnich, Dinah
Subject: Congrats

Dinah,

Did you see the below posting on DBPR website under Kudos to DBPR Employees.

Name: Tom Shupe

Employee Name(s): **Dinah Skrnich**

Employee Division: Drug Device and Cosmetics Program

Date: 1/9/2012

Details: I was renewing my authorization to purchase prescription drugs and contacted Ms. Skrnich to insure I had the right address to send request to. She advised that I could send it to her electronically and she could get it processed quickly. That was an understatement as she processed and returned my authorization in less than a day. Very good customer service.

Sincerely,

Ronda L. Bryan

Agency Clerk
Office of the General Counsel
Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, Florida 32399
Office (850) 717-1186
ronda.bryan@dbpr.state.fl.us

Mission: License efficiently. Regulate Fairly.

Vision: We make DBPR and Florida great places to do business. To that end we will invest in our employees, treat our licensees as valued customers and partners, and uphold laws that protect the public and Florida's competitive marketplace.

Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

2/28/2012

TAB 4. CONTROLLED SUBSTANCE REPORTING- KRISTEN GROSH

CSR Controlled Substances Reporting System

Since 07/1/2011

Distributors Reported = 282

Potential = 1,550

Reporters= 321

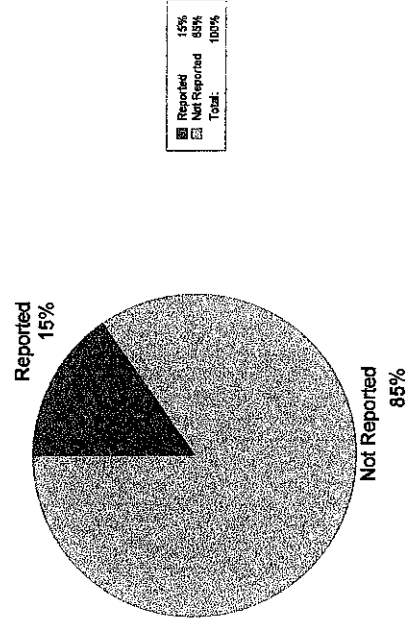
Files Uploaded= 2,831

Production= 2,135

Test= 695

Transactions= 5,209,836

Number of Potential Reported Distributions



TAB 5. OTHER BUSINESS