State of Florida Department of Business and Professional Regulation Division of Drugs, Devices and Cosmetics

Application for Veterinary Prescription Drug Wholesale Distributor Permit Form No.: DBPR-DDC-216

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

| APPLICATION | APPLICATION REQUIREMENTS |
|---|---|
| | ☐ Establishments* located in the state of Florida, enclose non-refundable \$1,150.00 fee, which includes a \$1,000.00 biennial application fee and a \$150.00 initial application/on-site inspection fee. ☐ Establishments* located outside the state of Florida, enclose non- |
| | refundable \$1,000.00 biennial application fee. |
| Application for Veterinary Prescription Drug Wholesale | ☐ Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation or DBPR. |
| Distributor Permit | ☐ If the applicant answered "Yes" to any question in Section IV, enclose a detailed explanation along with any relevant documentation. |
| | Sign and date the Affidavit section of the application. |
| | *Florida law generally defines "establishment" to mean a place of business at one general physical location. As used in this application, "the establishment" refers to the physical address of the establishment to be permitted. |
| | Submit the completed application with enclosures to: Department of Business and Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047 |

PLEASE NOTE:

Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.

The disclosure of Social Security numbers is mandatory on all professional and occupational license applications, is solicited by the authority granted by 42 U.S.C. §§ 653 and 654, and will be used by the Department of Business and Professional Regulation pursuant to §§ 409.2577, 409.2598, 499.012(4)(a)5.f., 499.012(8)(o), 499.63(2), and 559.79(3), Florida Statutes, for the efficient screening of applicant and licensees by a Title IV-D child support agency to assure compliance with child support obligations. It is also required by §559.79(1), Florida Statutes, for determining eligibility for licensure and mandated by the authority granted by 42 U.S.C. § 405(c)(2)(C)(i), to be used by the Department of Business and Professional Regulation to identify licensees for tax administration purposes.

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Application for Veterinary Prescription Drug Wholesale Distributor Permit Form No.: DBPR-DDC-216

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at **850.717.1800**. *For additional information* see the Instructions at the beginning of this application.

CHECK ONE OF THE APPLICATION TYPES

Section I- Application Type

| ONE OF THE ATTERATION THE ES |
|---|
| New Application [3342/1020] New Application due to Change in Ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3342/1020] Current Permit Number |
| Section II – Applicant Information |
| APPLICANT INFORMATION |
| TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER |
| This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN). |
| Applicant's TIN/FEIN: |
| FULL LEGAL NAME |
| The "full legal name" is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation's full legal name would normally be the name that is found in the corporation's articles of incorporation. |
| Applicant's Full Legal Name: |
| FICTITIOUS, TRADE OR BUSINESS NAME If the applicant intends to operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a "dba", or "doing business as" name), this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities. |
| The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above. |
| ☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: |
| The fictitious, trade, or business name listed directly above is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: |

APPLICANT'S MAILING ADDRESS

| Street Address or P.O. Box: | | | | |
|---|---|-------------------------------|--|--|
| City: | State: | Zip Code (+4 optional): | | |
| PHYSICAL ADDRESS OF ESTAI | BLISHMENT TO BE PE | RMITTED | | |
| Street Address: | | | | |
| City: | State: | Zip Code (+4 optional): | | |
| County (if Florida address): Country: | | | | |
| Telephone Number: | Fax Number: | | | |
| Email Address: | | | | |
| APPLICATIO | N CONTACT | | | |
| The application contact is the person that the departr responses provided on or the documentation submitted also the person that will receive all official communications. | ed with the application. | The application contact is | | |
| Last/Surname: First: | Middle: | Suffix: | | |
| Address: | | | | |
| City: | State: | Zip Code (+4 optional): | | |
| Telephone Number: | Fax Number: | • | | |
| E-Mail Address: | | | | |
| | Y CONTACT | | | |
| The emergency contact is the person that the dep During an emergency, the department may contact hours listed below. The contact information provided communicate with the person listed in the event of an | this person at times ou should be sufficient for | tside of the regular business | | |
| Last/Surname: First: | Middle: | Suffix: | | |
| Position/Title: | | | | |
| Street Address: | | | | |
| City: | State: | Zip Code (+4 optional): | | |
| Telephone Number: E-Mail Address: | | | | |
| OPERATING HOURS | | | | |
| List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below. The establishment must be open a minimum of 10 total hours per week (M-F) between 8:00 a.m. and 5:00 p.m., and at least 2 consecutive hours on at least 1 day: | | | | |
| Mon: am/pm to: am/pm | Fri: am/p | om to:am/pm | | |
| Tue:am/pm to:am/pm | Sat: am/p | | | |
| Wed:am/pm_to:am/pm | Sun: am/p | om to: am/pm | | |
| Thu:am/pm_to:am/pm | | | | |

Section III – Ownership Information

| | | TYP | OF OWNERSHIP | | | | |
|--------------|---|----------------|---|----------------------------|-----------------------|-------------------|---------------------|
| ☐ F | Publicly Held Corporation | | Closely Held Corporati | ion | Lim | nited Lia | ability Company |
| | ☐ Charitable Organization—501(c)(3) ☐ S | | Sole Proprietorship | | ☐ Go | vernme | ent |
| | | | Professional Corporati ssociation | ion | | fessior y Com | nal Limited pany |
| Limi | Partnership – Other, Including ted Liability Partnership and ted Partnership | | Other: | | | | |
| | the state of incorporation or state of orietorship). Business entities organi | | inder non-U.S. laws lis | st the c | country | of orga | |
| Stat | e or Country: | | | | | | 1 1/ |
| Part Flor | the name and address of the appli- nership – General or Sole Proprieto ida Department of State, Division of stered with the Florida Department of ne: | orship Corp |) and provide docum- porations' webpage, the e, Division of Corpora | entation hat the tions. | on, sucle e applic | n as a ant's r | print out from the |
| ۸۵۵ | ress: | | | | | | |
| | | | 10:: | | | - . | |
| | City: State: Zip code (+4 Optional): | | | | | | |
| men ope | the name, position/title, social securinber, manager, officer, director, chief ration of the business entity, as applictors, limited liability companies would | exec | cutive, or other person. For example, corpor | who d | directly would | or indir | ectly controls the |
| 1. | Name & Title: | | Social Security #: | | Date of | Birth: | % of Ownership: |
| | Street Address: | | City: | S | State: | | Zip Code: |
| 2. | Name & Title: | | Social Security #: | | Date of | Birth: | % of Ownership: |
| | Street Address: | | City: | S | State: | | Zip Code: |
| 3. | Name & Title: | | Social Security #: | С | Date of | Birth: | % of Ownership: |
| | Street Address: | | City: | S | State: | | Zip Code: |
| 4. | Name & Title: | | Social Security #: | Г | Date of | Birth: | % of Ownership: |
| | Street Address: | | City: | 5 | State: | | Zip Code: |

| 5. | Name & Title: | Social Security #: | Date of Birth: | % of Ownership: |
|----|--|-----------------------|------------------------|-------------------------------------|
| | Street Address: | City: | State: | Zip Code: |
| 6. | Name & Title: | Social Security #: | Date of Birth: | % of Ownership: |
| | Street Address: | City: | State: | Zip Code: |
| 7. | Name & Title: | Social Security #: | Date of Birth: | % of Ownership: |
| | Street Address: | City: | State: | Zip Code: |
| 8. | Name & Title: | Social Security #: | Date of Birth: | % of Ownership: |
| | Street Address: | City: | State: | Zip Code: |
| | the name, social security number, date of | | | |
| | e of the outstanding stock or equity intere the business entity name, FEID/FEIN, and | | | |
| 1. | Name: | SSN/FEID/FEIN#: | Date of Birth: | % of Ownership: |
| | Street Address: | City: | State: | Zip Code: |
| 2. | Name: | SSN/FEID/FEIN#: | Date of Birth: | |
| | | | | % of Ownership: |
| | Street Address: | City: | State: | % of Ownership: Zip Code: |
| 3. | Street Address: Name: | City: SSN/FEID/FEIN#: | State: Date of Birth: | |
| 3. | | | | Zip Code: |
| 3. | Name: | SSN/FEID/FEIN#: | Date of Birth: | Zip Code: % of Ownership: |
| | Name: Street Address: | SSN/FEID/FEIN#: City: | Date of Birth: State: | Zip Code: % of Ownership: Zip Code: |

| | Street Address: | City: | | State: | Zip Code: |
|--|--|--|-------------|----------------|-----------------|
| 6. | Name: | SSN/FEID/FEIN#: | | Date of Birth: | % of Ownership: |
| | Street Address: | City: | | State: | Zip Code: |
| 7. | Name: | SSN/I | FEID/FEIN#: | Date of Birth: | % of Ownership: |
| | Street Address: | City: | | State: | Zip Code: |
| 8. | Name: | SSN/F | FEID/FEIN#: | Date of Birth: | % of Ownership: |
| | Street Address: | City: | | State: | Zip Code: |
| | all trade or business names used by the a icant does not use other trade or busines | | | | |
| | | | | | |
| | | | | | |
| Is the applicant a subsidiary of another company? (If parent companies with percentages of ownership, us necessary. Note: A permit issued pursuant to this applicant, and the applicant's name and address.) | | ing additional shee oplicant is only vali | et(s) if | Yes No | |
| Parent Company Name | | % of Ownership | | | |
| | | | | | |
| | | | | | |

| appli mana partn appli or is five la | BACKGROUND QUESTIONS The term "affiliated party" means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant. If you answer "YES" to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s). | | | | | | |
|---|--|-------------|---|--|--|--|--|
| 1. | Yes If yes, explain in detail in Section V | ☐ No | Has the applicant or any "affiliated party" (defined above) been found guilty (regardless of adjudication) or pled nolo contendere in any jurisdiction of a violation of law that directly relates to a drug, device or cosmetic? | | | | |
| 2. | ☐ Yes If yes, explain in detail in Section V | □ No | Has the applicant or any "affiliated party" been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.? | | | | |
| 3. | ☐Yes If yes, explain in detail in Section V | ☐ No | Has the applicant or any "affiliated party" been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law? | | | | |
| 4. | ☐Yes If yes, explain in detail in Section V | □No | Has the applicant or any "affiliated party" been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.? | | | | |
| 5. | ☐Yes If yes, explain in detail in Section V | ☐ No | Has the applicant or any "affiliated party" had any current or previous permit or license suspended or revoked which was issued by a federal, state or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics? | | | | |
| 6. | ☐ Yes If yes, explain in detail in Section V | □ No | Has the applicant or any "affiliated party" ever held a permit issued under Chapter 499, F.S., in a different name than the applicant's name? If yes, provide the names in which each permit was issued and at what address. | | | | |
| 220 | - V Evalen | (2) 6 | | | | | |
| Sec | tion v – Expiana | ation(s) ic | or "Yes" response(s) to background question(s) EXPLANATION | | | | |
| | | | LAFLANATION | | | | |
| <u> </u> | | | | | | | |
| <u> </u> | | | | | | | |
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| _ | | | | | | | |
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Section VI – Other Permits or Licenses

| | PERMITS OR LICENSES | | | | | | |
|------|---|--|--------------------------------|--------------------|--|--|--|
| 1. | Are there any other permits or Florida that authorize the purc applicant's establishment or ac permit is issued, the permit typespaces provided below.) | Yes No | | | | | |
| 1.a. | Permit/License Name | Permit/License Type and Nui | Permit/License Type and Number | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 2. | from or into Florida? (If no, pro | u are applying sell veterinary prescripovide the name and address from white sold into Florida in the spaces pro if needed.) | ch the | Yes No | | | |
| 2.a. | Name | Physical Address | Florida Per | mit/License Number | | | |
| | | | | | | | |
| 3. | drugs into Florida? (If no, prov | l u are applying ship veterinary prescride the name and address of all locatings into Florida on your behalf in the all sheets if needed.) | ions that spaces | Yes No | | | |
| 3.a. | Name | Physical Address | Florida Per | mit/License Number | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 4. | Does the applicant intend to engage in the wholesale distribution of veterinary prescription drugs, which the applicant did not manufacture, which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act? (If yes, the applicant needs to be permitted as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, in lieu of a veterinary prescription drug wholesale distributor.) | | | | | | |

Section VII – Veterinary Prescription Drug Distribution Activity **DISTRIBUTION ACTIVITIES** Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance. ☐ Manufacturers Wholesalers Pharmacies ☐ Hospitals ☐ Practitioners 7 Clinics ☐ Veterinarians Other (explain): Identify the types of drugs the applicant will sell or distribute in or into Florida? (Check all that apply in the space below). ☐ Veterinary Prescription Drugs (approved for animal use only) Active Pharmaceutical Ingredients Note: If you sell or distribute any prescription drugs approved for human use, you do not qualify for this permit. Are products distributed under this permit intended for export? ☐Yes (Note: A permit may be required for freight forwarders handling products in Florida.) Are all required records stored and maintained at applicant's physical ☐ Yes address? (If no, provide the establishments address where all required records will be stored and maintained below.) 3. Physical address where required records are stored Street Address: City: State: Zip Code (+4 optional):

Are the required records computerized, automated or stored electronically?

If yes, do you have a back-up procedure to be able to provide required

Is the applicant a private label distributor of veterinary prescription drugs?

Does the applicant, the applicant's parent, sister or subsidiary companies.

or rehabilitative care? If so, please list all company/companies on a

provide diagnostic, medical, surgical, or dental treatment or care, or chronic

Do you understand that freight forwarders in Florida exporting for you or your

Does the applicant manufacture veterinary prescription drugs?

Does the applicant repackage veterinary prescription drugs?

customer need a permit under Chapter 499, F.S?

records?

separate sheet(s).

5.

6.

7.

8.

Yes

Yes

☐ Yes

☐ Yes

☐ Yes

☐ Yes

☐ Yes ☐ No

☐ No

☐ No

□No

☐ No

□ No

□No

Section VIII - If Located in the State of Florida

| | DISTRIBUTION ACTIVITIES | | | | | |
|----|--|---|--|--|--|--|
| 1. | Section 499.0121(2), F.S., requires establishments to be equipped with: a) an alarm system to detect entry after hours and b) a security system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. Please provide a written description of the alarm and security systems that includes both the type of systems used and how the systems are monitored. Alarm system description included? Security system description included? | ☐ Yes ☐ No | | | | |
| 2. | Is there a quarantine area at the applicant's establishment? (If not, please explain on a separate sheet.) Explanation included? Yes No | Yes No | | | | |
| 3. | Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's distributed products) to ensure safe storage? (If not, please explain on a separate sheet.) Explanation included? Yes No | ☐ Yes ☐ No | | | | |
| 4. | Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring? | Yes No | | | | |
| | Please provide copies of the applicant's written policies and procedures on: | Policy Attached? | | | | |
| | a. Receipt, security, storage, inventory, distribution/disposition of prescription drugs. | ☐ Yes ☐ No | | | | |
| | b. Distributing oldest approved stock first (FIFO). c. Identifying, recording and reporting prescription drug losses and thefts. | ☐ Yes ☐ No ☐ Yes ☐ No | | | | |
| | d. Maintenance, retrieval and retention of required records. e. Prescription drug recalls and withdrawals. f. Natural disasters and other emergencies. g. Segregation and destruction of outdated prescription drugs. h. Temperature and humidity monitoring. i. Product tracing and other DSCSA requirements. | Yes No Yes No Yes No Yes No Yes No Yes No | | | | |
| 5. | Provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete. | //20 | | | | |

Section IX- If located in a state other than Florida

| | DISTRIBUTION ACTIVITIES | | | | | |
|------|---|----------------|--|--|--|--|
| 1. | 1. Provide a valid license/permit number issued by your resident state that authorizes the sale/distribution of prescription drugs from the applicant's address. Attach a copy. | | | | | |
| 1.a. | Type of Permit: | Permit Number: | | | | |
| 2. | 2. Provide the name, address, and telephone number of the regulatory entity in the resident state that issues the above license/permit. | | | | | |

| | State Agency Name: | | | | |
|---|--|--------|-----------|--|--|
| 2.a. | Address: | | | | |
| | City: | State: | Zip Code: | | |
| 2.b. | Telephone Number: | | | | |
| Section | on X – Affidavit | | | | |
| | AFFIDA | VIT | | | |
| Depar applica require Pursua Regula oath o addres applica | Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law. Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law. | | | | |
| regula | I understand that the issuance of a permit by the department only authorizes the applicant to conduct regulated activities in the state of Florida under the name in which the permit is issued. If the permit is issued in the name of a dba the applicant may only conduct business in Florida in the name of the dba. | | | | |
| I further understand that providing additional dba names to the department as part of the application process is not, upon licensure, an authorization to conduct business in Florida under the name of those additional dba's. | | | | | |
| I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license. | | | | | |
| Signat | ture of Owner or Officer: | Date: | | | |
| Print N | Name: | Title: | | | |

Mail completed application to:

Department of Business and Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047