Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056 pharmacy@ks.gov Fax (785) 296-8420	**REGISTRATION APPLICATION:** **Manufacturer** Form BA-04

All applications must be typed, be complete, and include all fees and supporting documentation before they will be processed by staff.

FEES

Enclose a check or money order payable to the Kansas State Board of Pharmacy in the amount of $350.00. Fees are nonrefundable.

INSTRUCTIONS

This form may be used for resident and non-resident manufacturers, as well as virtual manufacturers.

The following documents are required for the application to be complete:

- ☐ Copy of current registration or permit issued by state of residence
- ☐ List of other states in which registered, with permit numbers
- ☐ S-350 Non-Resident Information form
- ☐ S-300 Disciplinary History form and explanation documents if any Discipline Information questions are answered "yes"
- ☐ S-310, S-320 or S-330 ownership forms and/or business organization chart, along with supporting ownership documents (refer to top of individual forms for requirement). See Ownership information below for further detail.
- ☐ Facility inspection report conducted at current physical location within the past 3 years by state of residence or the FDA
  - ☐ For virtual manufacturers, provide inspection by the state of residence, the FDA, or an NABP Supply Chain inspection

In addition to all requirements listed above, virtual manufacturers must provide:

- ☐ list of all contract manufacturers with name, address, email address, and FEI number
- ☐ list of all products manufactured

OWNERSHIP

The Owner is considered the "applicant" for purposes of this form. If the Owner is a corporate or other legal entity, please complete and attach the appropriate Ownership Form (S-310 Partnership, S-320 LLC, or S-330 Corporate). If owned by other LLCs, partnerships, holding companies, etc., please submit information down to a person level of ownership.

Please indicate if this is a new application or a change:

☐ New Application Change (Check all that apply): ☐ Address ☐ Ownership ☐ Name

Previous registration number: _____ Effective date of change: _____

OWNER INFORMATION

Name			
Address			
City	State	Zip	County
Phone	Fax		Email

Ownership Type:

☐ Individual Provide SSN: _____ ☐ Government Entity Provide FEIN: _____

☐ Partnership ☐ LLC ☐ Corporation

Complete and attach the appropriate Ownership Form (S-310 Partnership, S-320 LLC, or S-330 Corporate)

Initials: _____ **OFFICE USE ONLY**

Permit #: _____ Fee: $_____ Date: _____ Check #: _____

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MANUFACTURING FACILITY/OFFICE INFORMATION

Trade/Business Name (printed on license)		Hours of Operation	
Physical Address (non-residential)			
City	State	Zip	County
Phone	Fax		Email

Designate where all formal correspondence, notices, and renewals should be sent:

☐ Owner ☐ Physical Location ☐ Authorized Agent

DESIGNATED REPRESENTATIVE INFORMATION (This should be an individual preferably at the facility)

Name		Title	
Address			
City	State	Zip	County
Phone	Fax		Email

DRUG SCHEDULES (Check all that apply)

- ☐ Legend drugs
- ☐ Controlled substances
- ☐ Nonprescription drugs
- ☐ Schedule II narcotic
- ☐ Schedule II non-narcotic
- ☐ Schedule III narcotic
- ☐ Schedule III non-narcotic
- ☐ Schedule IV
- ☐ Schedule V (includes pseudoephedrine, ephedrine)
- ☐ Other: _____

If you selected any Drug Schedules above, please provide either:

☐ A copy of the current DEA Registration
Current DEA Registration Number _____ Expiration Date _____

☐ The submission date for the pending DEA Registration Application _____

☐ Yes ☐ No **Is the applicant currently registered with the FDA?**
If yes, provide your FDA Registration Number _____ Expiration Date _____

PRACTICE QUESTIONS

☐ Yes ☐ No Are you operating as a virtual manufacturer?
If yes:
- ☐ Yes ☐ No Are you required to register in your home state?
- ☐ Yes ☐ No Does the virtual office have adequate lighting, ventilation, temperature controls, humidity, space, equipment, sanitation, and security, and is the facility free of any infestation and maintained in a clean and orderly condition?

☐ Yes ☐ No Are all Kansas businesses or individuals you conduct business with licensed or registered to possess drugs or devices in Kansas?

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DISCIPLINARY INFORMATION

Applicant includes the legal ownership entity as well as each individual, owner, partner, corporate officer, or director.

☐Yes ☐No **1.** Has the applicant been convicted under any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, manufacturing, dispensing, or distribution of any drug or controlled substance?

☐Yes ☐No **2.** Has the applicant been convicted of or entered a plea of no contest to any felony?

☐Yes ☐No **3.** Has any license or registration, currently or previously held by the applicant been denied, disciplined, censured, revoked, suspended, or surrendered for the dispensing, manufacture or distribution of any drug or controlled substance?

☐Yes ☐No **4.** Has the applicant ever furnished false or fraudulent material on any application made in connection with the dispensing, manufacture or distribution of any drug?

If yes to any of the above questions, please attach Form S-300: Disciplinary History.

☐Yes ☐No **5.** Has the applicant complied with all registration requirements under any previous or current licenses or registrations?

☐Yes ☐No **6.** Has the applicant complied with all requirements to maintain and make available to the Board or to any federal, state, or local law enforcement officials those records required by the Food, Drug, and Cosmetic Act?

☐Yes ☐No **7.** Has each employee or associate engaged in any prescription drug wholesale distribution activity had education, training, or experience sufficient for that individual to perform assigned functions in such a manner as to provide assurance that the drug product, quality, safety, and security will at all times be maintained as required by any federal or state law?

If no to any of the above questions, please attach a detailed explanation along with any relevant documentation.

DESIGNATED REPRESENTATIVE CERTIFICATION

I declare under penalty of perjury under the laws of the State of Kansas that I understand any permit issued will be issued jointly to the applicant and myself, and I hereby accept responsibility as the designated representative for such permit, which shall include compliance with the Kansas Pharmacy Act and Kansas Controlled Substances Act.

SIGNATURE _____ DATE SIGNED _____

OWNER CERTIFICATION

I declare under penalty of perjury under the laws of the State of Kansas that I have read and understand this application and that the information provided is true, correct, and complete to the best of my knowledge.

SIGNATURE _____ DATE SIGNED _____