

§ 1301.15

21 CFR Ch. II (4-1-20 Edition)

§ 1301.15 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

[62 FR 13948, Mar. 24, 1997]

§ 1301.16 Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to §1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

[62 FR 13949, Mar. 24, 1997]

§ 1301.17 Special procedures for certain applications.

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing agency, the applicant may include with his/her application an affidavit as to the existence of the State license in the following form:

Affidavit for New Pharmacy

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) at _____

_____, (Number and Street), _____ (City) _____ (State) _____ (Zip code), hereby certify that said store was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ on _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000 or both.

Signature (Person who signs Application for Registration) _____
State of _____
County of _____

Subscribed to and sworn before me this _____ day of _____, 19____.

Notary Public _____

(b) Whenever the ownership of a pharmacy is being transferred from one person to another, if the transferee owns at least one other pharmacy licensed in the same State as the one the ownership of which is being transferred, the transferee may apply for registration prior to the date of transfer. The Administrator may register the applicant and authorize him to obtain controlled substances at the time of transfer. Such registration shall not authorize the transferee to dispense controlled substances until the pharmacy has been issued a valid State license. The transferee shall include with his/her application the following affidavit:

Affidavit for Transfer of Pharmacy

I, _____, the _____ (Title of officer, official, partner or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy of Licensing Agency) of the State of _____ and a DEA Registration Number _____ for a pharmacy located at _____