

Drug Enforcement Administration, Justice

§ 1301.17

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(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.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

(2) That said company is acquiring the pharmacy business of _____ (Name of Seller) doing business as _____ with DEA Registration

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Number _____ on or about _____
(Date of Transfer) and that said company has
applied (or will apply on _____ (Date)
for a pharmacy permit from the board of
pharmacy (or licensing agency) of the State
of _____ to do business as
_____ (Store name) at
_____ (Number and Street)
_____ (City) _____ (State)
_____ (Zip Code).

This statement is submitted in order
to obtain a Drug Enforcement Admin-
istration registration number.

I understand that if a DEA registration
number is issued, the pharmacy may acquire
controlled substances but may not dispense
them until a pharmacy permit or license is
issued by the State board of pharmacy or li-
censing agency.

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 affi-
davit may subject me personally to prosecu-
tion 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

(c) The Administrator shall follow
the normal procedures for approving an
application to verify the statements in
the affidavit. If the statements prove to
be false, the Administrator may re-
voke the registration on the basis of
section 304(a)(1) of the Act (21 U.S.C.
824(a)(1)) and suspend the registration
immediately by pending revocation on
the basis of section 304(d) of the Act (21
U.S.C. 824(d)). At the same time, the
Administrator may seize and place
under seal all controlled substances
possessed by the applicant under sec-
tion 304(f) of the Act (21 U.S.C. 824(f)).
Intentional misuse of the affidavit pro-
cedure may subject the applicant to
prosecution for fraud under section
403(a)(4) of the Act (21 U.S.C. 843(a)(4)),
and obtaining controlled substances
through registration by fraudulent
means may subject the applicant to

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prosecution under section 403(a)(3) of
the Act (21 U.S.C. 843(a)(3)). The pen-
alties for conviction of either offense
include imprisonment for up to 4 years,
a fine not exceeding \$30,000 or both.

[62 FR 13949, Mar. 24, 1997]

§ 1301.18 Research protocols.

(a) A protocol to conduct research
with controlled substances listed in
Schedule I shall be in the following
form and contain the following infor-
mation where applicable:

(1) Investigator:

(i) Name, address, and DEA registra-
tion number; if any.

(ii) Institutional affiliation.

(iii) Qualifications, including a cur-
riculum vitae and an appropriate bibli-
ography (list of publications).

(2) Research project:

(i) Title of project.

(ii) Statement of the purpose.

(iii) Name of the controlled sub-
stances or substances involved and the
amount of each needed.

(iv) Description of the research to be
conducted, including the number and
species of research subjects, the dosage
to be administered, the route and
method of administration, and the du-
ration of the project.

(v) Location where the research will
be conducted.

(vi) Statement of the security provi-
sions for storing the controlled sub-
stances (in accordance with §1301.75)
and for dispensing the controlled sub-
stances in order to prevent diversion.

(vii) If the investigator desires to
manufacture or import any controlled
substance listed in paragraph (a)(2)(iii)
of this section, a statement of the
quantity to be manufactured or im-
ported and the sources of the chemicals
to be used or the substance to be im-
ported.

(3) Authority:

(i) Institutional approval.

(ii) Approval of a Human Research
Committee for human studies.

(iii) Indication of an approved active
Notice of Claimed Investigational Ex-
emption for a New Drug (number).

(iv) Indication of an approved funded
grant (number), if any.

(b) In the case of a clinical investiga-
tion with controlled substances listed