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 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 Administration 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 licensing 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 affidavit may subject me personally 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

(c) If at the time of application for a separate registration at a long term care facility, the retail pharmacy has been issued a license, permit, or other form of authorization from the appropriate State agency to install and operate an automated dispensing system for the dispensing of controlled substances at the long term care facility, the applicant must include with his/her application for registration (DEA Form 224) an affidavit as to the existence of the State authorization. Exact language for this affidavit may be found at the DEA Diversion Control Program Web site. The affidavit must include the following information:

(1) The name and title of the corporate officer or official signing the affidavit;

(2) The name of the corporation, partnership or sole proprietorship operating the retail pharmacy;

(3) The name and complete address (including city, state, and Zip code) of the retail pharmacy;

(4) The name and complete address (including city, state, and Zip code) of the long term care facility at which DEA registration is sought;

(5) Certification that the named retail pharmacy has been authorized by the state Board of Pharmacy or licensing agency to install and operate an automated dispensing system for the dispensing of controlled substances at the named long term care facility (including the license or permit number, if applicable);

(6) The date on which the authorization was issued;

(7) Statements attesting to the following:

(i) The affidavit is submitted to obtain a Drug Enforcement Administration registration number;

(ii) If any material information is false, the Administrator may commence proceedings to deny the application under section 304 of the Act (21 U.S.C. 824(a));

(iii) Any false or fraudulent material information contained in this affidavit may subject the person signing this affidavit and the above-named corporation/partnership/business to prosecution under section 403 of the Act (21 U.S.C. 843);

(8) Signature of the person authorized to sign the Application for Registration for the named retail pharmacy;

(9) Notarization of the affidavit.

(d) 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 revoke 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 section 304(f) of the Act (21 U.S.C. 824(f)). Intentional misuse of the affidavit procedure 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 prosecution under section 403(a)(3) of the Act (21 U.S.C. 843(a)(3)). The penalties 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, as amended at 70 FR 25465, May 13, 2005]

§ 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 information where applicable:

(1) Investigator:

(i) Name, address, and DEA registration number; if any.

(ii) Institutional affiliation.

(iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:

(i) Title of project.

(ii) Statement of the purpose.

(iii) Name of the controlled substances 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