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 method of administration, and the duration of the project.

(v) Location where the research will be conducted.

(vi) Statement of the security provisions for storing the controlled substances (in accordance with §1301.75) and for dispensing the controlled substances 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 imported and the sources of the chemicals to be used or the substance to be imported.

(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 Exemption for a New Drug (number).

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

(b) In the case of a clinical investigation with controlled substances listed in Schedule I, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as proscribed in paragraph (a)(2)(vi) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and §130.3 of this title. Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in paragraph (a) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on _____ (Date), pursuant to 21 U.S.C. 355(i) and 21 CFR 130.3, I, _____ (Name and Address of IND Sponsor) submitted a Notice of Claimed Investigational Exemption for a New Drug (IND) to the Food and Drug Administration for:

_____

(Name of Investigational Drug).

_____

(Date)

_____

(Signature of Applicant).

(c) In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, by registered mail, return receipt requested. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. The request shall contain the following information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request. The Administration shall review the letter and forward it to the Food and Drug Administration together with the Administration comments. The Food and Drug Administration shall approve or deny the request as an amendment to the protocol and so notify the registrant. Approval of the letter by the Food and Drug Administration shall authorize the registrant to use the additional quantity of the controlled substance in the research project.

(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant's approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in paragraph

(c) of this section), he/she shall submit three copies of a supplemental protocol in accordance with paragraph (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Supplemental protocols shall be processed and approved or denied in the same manner as original research protocols.

[62 FR 13949, Mar. 24, 1997, as amended at 75 FR 10676, Mar. 9, 2010]

§ 1301.19 Special requirements for online pharmacies.

(a) A pharmacy that has been issued a registration under § 1301.13 may request that the Administrator modify its registration to authorize the pharmacy to dispense controlled substances by means of the Internet as an online pharmacy. The Administrator may deny an application for a modification of registration if the Administrator determines that the issuance of a modification would be inconsistent with the public interest. In determining the public interest, the Administrator will consider the factors listed in section 303(f) of the Act (21 U.S.C. 823(f)).

(b) Each online pharmacy shall comply with the requirements of State law concerning licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses, or offers to deliver, distribute, or dispense controlled substances by means of the Internet.

(c) Application for a modified registration authorizing the dispensing of controlled substances by means of the Internet will be made by an online application process as specified in § 1301.13 of this part. Subsequent online pharmacy registration renewals will be accomplished by an online process.

(d) A pharmacy that seeks to discontinue its modification of registration authorizing it to dispense controlled substances by means of the Internet as an online pharmacy (but continue its business activity as a non-online pharmacy) shall so notify the Administrator by requesting to modify its registration to reflect the appropriate business activity. Once the registration has been so changed, the pharmacy may no longer dispense controlled substances by means of the Internet. A pharmacy that has so changed its registration status back to that of a non-online pharmacy remains responsible for submitting reports in accordance with § 1304.55 of this chapter with respect to any controlled substances that it dispensed while it was registered with a modification authorizing it to operate as an online pharmacy.

(e) Registrants applying for modified registrations under this section must comply with notification and reporting requirements set forth in §§ 1304.40, 1304.45, 1304.50, and 1304.55 of this chapter.

(f) No person (including a registrant) required to obtain a modification of a registration under §§ 1301.11(b) and 1301.13 of this part authorizing it to operate as an online pharmacy may engage in any activity for which such modification of registration is required until the application for such modified registration is granted and an active Certificate of Registration indicating the modification of the registration has been issued by the Administrator to such person.

[74 FR 15622, Apr. 6, 2009]

EXCEPTIONS TO REGISTRATION AND FEES

§ 1301.21 Exemption from fees.

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration:

(1) Any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps., Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(2) Any individual practitioner who is required to obtain an individual registration in order to carry out his or her duties as an official of an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) In order to claim exemption from payment of a registration or reregistration application fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior (if