individual practitioner involved meets all requirements for a waiver under section 303(g)(2)(B) of the Act (21 U.S.C. 823(g)(2)(B)). Health and Human Services will notify DEA of its determination regarding the individual practitioner. If the individual practitioner has the appropriate registration under §1301.13, then the Administrator will issue the practitioner an identification number as soon as one of the following conditions occurs:

(i) The Administrator receives a positive determination from the Secretary of Health and Human Services before the conclusion of the 45-day review period, or

(ii) The 45-day review period has concluded and no determination by the Secretary of Health and Human Services has been made.

(2) If the Secretary denies certification to an individual practitioner or withdraws such certification once it is issued, then DEA will not issue the individual practitioner an identification number, or will withdraw the identification number if one has been issued.

(3) The individual practitioner must include the identification number on all records when dispensing and on all prescriptions when prescribing narcotic drugs under this section.

(e) An individual practitioner may begin to prescribe or dispense narcotic drugs to a specific individual patient under this section before receiving an identification number from the Administrator if the following conditions are met:

(1) The individual practitioner has submitted a written notification under paragraph (b) of this section in good faith to the Secretary of Health and Human Services.

(2) The individual practitioner reasonably believes that the conditions specified in paragraphs (b) and (c) of this section have been met.

(3) The individual practitioner reasonably believes that the treatment of an individual patient would be facilitated if narcotic drugs are prescribed or dispensed under this section before the sooner of:

(i) Receipt of an identification number from the Administrator, or

(ii) Expiration of the 45-day period.

(4) The individual practitioner has notified both the Secretary of Health and Human Services and the Administrator of his or her intent to begin prescribing or dispensing the narcotic drugs before expiration of the 45-day period.

(5) The Secretary has not notified the registrant that he/she is not qualified under paragraph (d) of this section.

(6) The individual practitioner has the appropriate registration under §1301.13.

(f) If an individual practitioner dispenses or prescribes Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment in violation of any of the conditions specified in paragraphs (b), (c) or (e) of this section, the Administrator may revoke the individual practitioner's registration in accordance with §1301.36.

[70 FR 36342, June 23, 2005, as amended at 73 FR 29688, May 22, 2008; 83 FR 3074, Jan. 23, 2018; 85 FR 69166, Nov. 2, 2020]

§1301.29 [Reserved]

Action on Application for Registration: Revocation or Suspension of Registration

§1301.31 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 303 (21 U.S.C. 823) or section 1008 (21 U.S.C. 958) of the Act have been met by the applicant.

[62 FR 13953, Mar. 24, 1997]

§1301.32 Action on applications for research in Schedule I substances.

(a) In the case of an application for registration to conduct research with controlled substances listed in Schedule I, the Administrator shall process the application and protocol and forward a copy of each to the Secretary of

Health and Human Services (Secretary) within 7 days after receipt. The Secretary shall determine the qualifications and competency of the applicant, as well as the merits of the protocol (and shall notify the Administrator of his/her determination) within 21 days after receipt of the application and complete protocol, except that in the case of a clinical investigation, the Secretary shall have 30 days to make such determination and notify the Administrator. The Secretary, in determining the merits of the protocol, shall consult with the Administrator as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use.

(b) An applicant whose protocol is defective shall be notified by the Secretary within 21 days after receipt of such protocol from the Administrator (or in the case of a clinical investigation within 30 days), and he/she shall be requested to correct the existing defects before consideration shall be given to his/her submission.

(c) If the Secretary determines the applicant qualified and competent and the research protocol meritorious, he/she shall notify the Administrator in writing of such determination. The Administrator shall issue a certificate of registration within 10 days after receipt of this notice, unless he/she determines that the certificate of registration should be denied on a ground specified in section 304(a) of the Act (21 U.S.C. 824(a)). In the case of a supplemental protocol, a replacement certificate of registration shall be issued by the Administrator.

(d) If the Secretary determines that the protocol is not meritorious and/or the applicant is not qualified or competent, he/she shall notify the Administrator in writing setting forth the reasons for such determination. If the Administrator determines that grounds exist for the denial of the application, he/she shall within 10 days issue an order to show cause pursuant to §1301.37 and, if requested by the applicant, hold a hearing on the application pursuant to §1301.41. If the grounds for denial of the application include a determination by the Secretary, the Secretary or his duly authorized agent shall furnish testimony and documents pertaining to his determination at such hearing.

(e) Supplemental protocols will be processed in the same manner as original research protocols. If the processing of an application or research protocol is delayed beyond the time limits imposed by this section, the applicant shall be so notified in writing.

[62 FR 13953, Mar. 24, 1997]

§1301.33 Application for bulk manufacture of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, the Administrator shall, upon the filing of such application, publish in the FEDERAL REGISTER a notice naming the applicant and stating that such applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 60 days from the date of publication of the notice in the FEDERAL REGISTER, file with the Administrator written comments on or objections to the issuance of the proposed registration.

(b) In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

(c) Except as provided in paragraph (d) of this section, this section shall not apply to the manufacture of basic classes of controlled substances listed in Schedule I or II as an incident to research or chemical analysis as authorized in § 1301.13(e)(1).

(d) An application for registration to manufacture marihuana that involves the planting, cultivating, growing, or harvesting of marihuana shall be subject to the requirements of this section