Proposed Rule Making

DEPARTMENT OF THE TREASURY

Monetary Offices [31 CFR Part 103]

FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

Notice of Effective Date

Notice is hereby given that, pursuant to the authority contained in section 401(b), title IV, of Public Law 91-508, 84 Stat. 1125, the provisions of titles I and II of said Act and all amendments made thereby, shall become effective on November 1, 1971. Section 103-49 of the proposed regulations which were published in the June 10th Federal Register (36 FR 11211) is modified accordingly.

S. E. Pringle, Jr.,
General Counsel.

JULY 15, 1971.

DEPARTMENT OF JUSTICE

Bureau of Narcotics and Dangerous Drugs


NARCOTICS AND DANGEROUS DRUGS

Notice of Proposed Rule Making

Under the authority vested in the Attorney General by sections 201(a), 301(g), 302(d), 301, 302(c), 304, 305, 310(c), 307, 308, 301(b), 305, 511, 513, 725(c), 705, 1002, 1003, 1004, 1006, 1007(b), 1008(d), 1008(e), and 1015 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and delegated to the Director, Bureau of Narcotics and Dangerous Drugs, by §100 of Title 28 of the Code of Federal Regulations, the Director hereby proposes that Parts 301, 302, 303, 305, 306, 307, 308, and 311 of Title 21 of the Code of Federal Regulations be amended as follows:

1. By amending §301.13 by adding the words “or which” immediately after the word “who” in paragraphs (a) (1) and (2), by adding the words “or her” immediately after the word “his” in paragraph (a) (2), and by adding the words “(if an individual) or officer (if an agency)” immediately after the word “employer” in paragraph (b).

2. By amending §301.22 as follows:

(a) By deleting paragraphs (a) (3) and (4) and replacing these subparagraphs with the following:

(3) Dispensing, conducting research (other than research described in sub-
paragraph (4) of this paragraph) with, and conducting instructional activities with, controlled substances listed in schedules II through V;

(b) By the words “preclinical research (including quality)” immediately after the words “chemical analysis and” in paragraph (b) (2); and

(c) By adding the words “and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances” at the end of paragraph (b) (3); and

(d) By adding the words “or authorized” immediately after the words “a person registered” by adding the words “or authorized” immediately after the words “other persons registered”, and by adding the words “or research with such substances,” after the words “instructional activities” in paragraph (b) (4); and

3. By amending §301.23 by substituting the words “registered locations other than the registered location from which the substances were delivered” for the words “registrants other than the registered person” in paragraph (b) (1).

4. By deleting §301.34 and replacing it with the following:

§301.24 Exemption of agents and employees; affiliated practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if said agent or employee is acting in the usual course of his business or employment.

(b) An individual practitioner (other than an intern, resident, or foreign physician) who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer, and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employer or principal practitioner in lieu of being registered himself. (For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances if a pharmacy is so registered.)

(c) An individual practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom he is employed provided that:

(1) Such dispensing or prescribing is done in the usual course of his professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he is practicing;

(3) The hospital or other institution by whom he is employed has determined that the individual practitioner is so permitted to dispense or prescribe drugs by the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his employment in the hospital or institution;

(5) The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital's registration and designates a specific internal code num-

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§ 301.43 Additional information during registration.

Any applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Branch of the Bureau a written statement signed by an attorney on BND Form 22a for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the nature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

§ 301.44 Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 29883, Central Station, Washington, DC 20005. The letter shall contain the registrant’s name, address, registration number, and the name of the controlled substances to be added to his registration, and shall be signed by the same person who signed the most recent application for registration or registration extension. If the registrant is requesting to handle additional controlled substances listed in schedule I for the purpose of research or instructional activities, he shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities attached to the form; and

§ 301.61 Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 29883, Central Station, Washington, DC 20005. The letter shall contain the registrant’s name, address, registration number, and the name of the controlled substances to be added to his registration, and shall be signed by the same person who signed the most recent application for registration or registration extension. If the registrant is requesting to handle additional controlled substances listed in schedule I for the purpose of research or instructional activities, he shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.

§ 301.64 Termination of provisional registration.

The registration of any person who is provisionally registered under section 702(a) of the Act (21 U.S.C. 822 note) and who have not been assigned a date for registration by August 31, 1971, shall terminate on October 1, 1971.

§ 301.71 Factors in evaluating physical security systems.

In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the Director may consider any of the following factors as he may deem relevant to the need for strict compliance with the requirements of §§ 301.73 and 301.75:

(a) The type of activity conducted;
(b) The quantity of controlled substances handled;
(c) The location of the premises and the relationship such location bears on security needs;
(d) The type of building construction comprising the facility and the general characteristics of the building or buildings;
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(e) The type of vault, safe, and secure enclosures available;
(f) The type of closures on vaults, safes, and secure enclosures;
(g) The adequacy of key control systems and/or combination lock control systems;
(h) The adequacy of electric detection and alarm systems, if any;
(i) The authorized public access to the facility, including the presence and characteristics of perimeter fencing, if any;
(j) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
(k) The availability of local police protection or of the registrant’s or applicant’s security personnel;
(l) The adequacy of the registrant’s or applicant’s system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

§ 301.73 Physical security controls for nonpractitioners.

(a) Storage areas. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances shall be stored in vaults or a safe where unauthorized entry shall be prevented; and in any schedule shall be stored in one of the following secure storage areas:
(1) Where small quantities permit, a safe;
(2) Which safe has an Underwriters’ Laboratories Burglary Rating of “2-20, E” or better, or the equivalent of such a safe;
(3) Which safe, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed;
(4) Which safe, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon unauthorized entry, shall transmit a signal directly to a central protection company of a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Director may approve.

(b) Vault construction. A vault constructed before January 1, 1972, which is of substantial construction, with the vault, combination or key lock, and an alarm system;

(c) A vault constructed after January 1, 1972:
(1) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced, vertically and horizontally with 1/2-inch steel rods tied 8 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
(2) The door of which vault contains a multiple-position combination lock or the equivalent, a relocking device or the equivalent, and steel plate with a thickness of at least 1 inch or with a 2-hour fire rating or the equivalent;
(3) Which vault has a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
(4) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Bureau may approve, and, if necessary, hold-up buttons at strategic points of entry to the perimeter area of the vault;
(5) The door of which vault is equipped with contact switches; and
(6) Which vault has one of the following: complete electrical fusing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Bureau.

(a) Controlled substances. All retrieval (ASR) equipment system which does not permit withdrawal or replacement of controlled substances except by a limited number of employees specifically authorized to do so, provided that the ASR system is located in a building which conforms to subparagraph (f) of this paragraph.

(b) For raw materials, bulk materials, and finished products which are controlled substances listed in schedules III, IV, and V, a building:
(1) Which has walls or perimeter fences of sufficient construction to provide security from burglary;
(2) Which has substantial doors which may be securely locked during nonworking hours by a multiple-position combination or key lock;
(3) Which is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Bureau may approve;
(4) In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(b) Manufacturing activities. All manufacturing activities (including processing, packaging, and labeling) involving controlled substances shall be conducted in accordance with the following:
(1) All in-process substances shall be returned to the secure storage area at the termination of the process. If the process is not terminated at the end of a workday (except in continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall be transmitted directly to a central protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

13. By amending § 301.74 as follows:

a. By adding a new sentence at the end of paragraph (d) to read as follows: “Theft must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.”

b. By adding the words “listed in schedules II through V” immediately after the words “controlled substance” in the first sentence of paragraph (d), by adding the words “and quantity” immediately after the words “and the name” in the second sentence of paragraph (d), by deleting the words “Schedules I or II in the fourth sentence of paragraph (d) and replacing these words with “schedule II,” and by adding a new sentence at the end of paragraph (d) to read as follows: “For purposes of this paragraph, the phrase ‘cardboard’ includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or manufacturing of the substance by the person.”

14. By amending § 301.76 by deleting the words “loss or theft” and replacing these words with the words “theft or significant loss” in paragraph (b).

15. By amending § 302.63 by deleting paragraph (g) of that section.

16. By adding a new section as follows:

§ 302.63 Labeling and packaging requirements for imported and exported substances.

(a) The symbol requirements of §§ 302.60-302.66 apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the jurisdiction of the United States, as defined in § 311.02 of this chapter.

(b) The symbol requirements of §§ 302.60-302.66 do not apply to any commercial containers containing, or
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any labeling of, a controlled substance intended for export from the jurisdiction of the United States, as defined in §311.02 of this chapter.

17. By amending §303.11 by deleting the words "in the form prescribed in part 310 of this chapter" and replacing these words with the words "in accordance with §303.34" at the end of the third sentence of paragraph (c), and by adding a new sentence at the end of paragraph (e) to read as follows: "Any interested person may participate in the hearing by filing a notice of appearance in accordance with §303.34."

18. By amending §303.12 as follows:

(a) By adding a new sentence between the first and second sentences of paragraph (d) to read as follows: "Such application shall be filed with the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537."

(b) By substituting the word "its" for the word "as" in the third sentence of paragraph (d).

(c) By revising paragraph (e) to read as follows:

(2) Any person who is registered or authorized to conduct chemical research with controlled substances (for controlled substances to be used in such analysis only); and

(d) By adding the words "or III" immediately after the words "schedule I", and by deleting the number "(2)" immediately after the numbers "301.22(b)", in paragraph (e) (3).

19. By amending §303.34 by adding at the end of paragraph (a) the following sentence: "Any person who desires a hearing on the determination of an aggregate production quota shall, within the time prescribed in §303.11, file with the written request for a hearing in the form prescribed in §161.47 of this chapter, including in the request a statement of the grounds for a hearing."

20. By amending §304.03 by adding at the end of paragraph (a) the following: "Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to §307.11 or pursuant to §§307.13-307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct those activities."

21. By amending §304.14 by deleting the words "manufacturing, distributing, or dispensing" and substituting the word "possesses."

22. By amending §304.15 by deleting the words "Each registered manufacturer at the beginning of the section and substituting the words "Each person registered or authorized (by §§301.22(b) or 307.15 of this chapter) to manufacture controlled substances."

23. By amending §304.16 by deleting the words "Each registered distributor" and substituting the words "Each person registered or authorized (by §§301.22(b) or 307.15 of this chapter) to distribute controlled substances."

24. By amending §304.17 by adding the words "or authorized (by §301.22(b) of this chapter)" immediately after the words "Each person registered" at the beginning of the section.

25. By amending §304.17 by deleting the words "Each registered importer or exporter" in the first sentence of the section and substituting the words "Each person registered or authorized (by §301.22(b) of this chapter) to import or export controlled substances," and by deleting the word "importer," and "exporter" in the second sentence of the section and substituting the words "Each such person."

26. By amending §304.18 as follows:

a. By deleting the words "Each analytical laboratory registered" at the beginning of the section and substituting the words "Each person registered or authorized (by §301.22(b) of this chapter)"

b. By deleting the words "its" in the first sentence of the section and substituting the words "his."

c. By deleting the words "laboratory conducting the inventory" at the end of the first sentence of the section and substituting the words "such person."

d. By adding at the end of the section the following sentence: "No inventory is required of known or suspected controlled substances received as evidentiary material."

27. By amending §304.22 as follows:

a. By deleting the words "Each registered manufacturer at the beginning of the section and substituting the words "Each person registered or authorized (by §§301.22(b) or 307.15 of this chapter) to manufacture controlled substances."

b. By revising subparagraph (b) (5) to read as follows: "The number of units of finished forms and/or commercial containers imported directly by the person having a registration or authorization to import, including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation."

28. By amending §304.24 as follows:

a. By deleting the words "Each registered distributor" and substituting the words "Each person registered or authorized (by §§301.22(b) or 307.15 of this chapter) to distribute controlled substances."

b. By revising paragraph (d) to read as follows:

(1) The number of commercial containers of each such finished form imported directly by the person (under a registration or authorization to import, including the date of, the number of commercial containers in, and the import permit or declaration number for, each importation);

(c) By revising paragraph (f) to read as follows:

(1) The number of commercial containers of each such finished form exported directly by the person (under a registration or authorization to export, including the date of, the number of commercial containers in, and the export permit or declaration number for, each exportation); and

(d) By deleting the word "registrant" in paragraph (f) and substituting the word "person," and by adding the words "or by destruction" immediately after the word "samples" within the parentheses in paragraph (g).

29. By amending §304.24 by adding the words "or authorized (by §301.22(b) of this chapter)" immediately after the words "Each person registered" at the beginning of the section.

30. By amending §304.25 by deleting the words "Each registered importer" and substituting the words "Each person registered or authorized (by §301.22(b) of this chapter) to import controlled substances."

31. By amending §304.26 by deleting the words "Each registered exporter" and substituting the words "Each person registered or authorized (by §301.22(b) of this chapter) to export controlled substances."

32. By amending §304.27 as follows:

a. By adding the words "or authorized (by §301.22(b) of this chapter)" immediately after the words "Each person registered."

b. By deleting paragraph (b) and redesignating paragraphs (c) and (d) to be (b) and (c) respectively.

c. By deleting the word "samples" in paragraph (d) and substituting the words "evidentiary material."

33. By amending §304.31 as follows:

a. By adding the words "listed in schedules I, II, and III" immediately after the words "narcotic controlled substances" in the following places:

(1) The first sentence of paragraph (a);

(2) The first sentence of paragraph (b);

(3) The first sentence of paragraph (c);

(4) The first sentence of paragraph (d);

(5) The second sentence of paragraph (d);

(6) The sixth sentence of paragraph (d);

(7) The eighth sentence of paragraph (d);

(8) The first sentence of paragraph (e) and;

(9) The first sentence of paragraph (f).

b. By deleting the words "listed in schedules III, IV, and V sold to practitioners" in the fifth sentence of paragraph (e) and substituting the words "listed in schedule III sold to dispensers."
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34. By amending § 304.32 as follows: a. By adding immediately after the words "registered distributor" the words "(except any officer or agency of the Veterans Administration or who or which is exempted from registration pursuant to § 301.25 (this chapter))."
b. By adding the words "listed in schedules I and II" immediately after the words "controlled substances," and by deleting the words "listed in schedules I and II" immediately after the word "exporter", in the first sentence of paragraph (b).c. By deleting the words "fourth quarterly" and substituting the words "December 31 monthly" in the first sentence of paragraph (d).d. By adding the words "(and exporter)" after the word "distributor" in paragraph (e).

35. By amending § 305.05 by deleting the following words from paragraph (d) : "and the Bureau Controlled Substances Code Number (set forth in Part 308 of this chapter) of the basic class of controlled substance listed in schedule I which the registrant is authorized to handle, if the case of order forms issued to a person registered to conduct chemical analysis with controlled substances listed in schedule I, the order forms shall not be confined to a single such substance and may be used to purchase any of such substances."e. By amending § 305.06 by deleting the last sentence of paragraph (b).f. By amending § 305.08 as follows: a. By adding the words "in accordance with § 307.14 of this chapter" at the end of paragraph (a).
b. By adding the words "or the manufacturer of the substance," immediately before the words "pursuant to" in paragraph (b).c. By deleting the number "§ 307.11" and substituting the numbers "§§ 307.11 or 307.12" in paragraph (c).

38. By amending § 305.09 by deleting the words "Armed Services Medical Procurement Agency" and substituting the words "Defense Personnel Support Center of the Defense Supply Agency" in paragraph (J).

39. By amending § 305.14 by deleting the words "any controlled substance listed in schedule I or II," and substituting the words "all controlled substances listed in schedules I and II for which he is registered.",

40. By amending § 306.02 by revising the definition of register in paragraph (e) as follows: a. By deleting the words "(and exporter)" and the words "(registration required and permitted by section 305 of the Act (21 U.S.C. 823)."

41. By amending § 306.03 by deleting the number "§ 301.25" in paragraph (a) and substituting the numbers "§§ 301.24 and 301.25."b. By amending § 306.05 by designating the existing paragraph as paragraph (a) and by adding new paragraphs as follows: (b) An intern, resident, or foreign physician exlminated from registration under § 301.24 shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution, and in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign physician or foreign health care facility as well as the signature of the physician. (c) An official exempted from registration under § 301.25 shall include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security Identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

43. By amending § 306.11 by adding the word "directly" immediately after the word "dispensing" in both paragraph (a) and paragraph (b).44. By amending § 306.22 as follows: a. By adding the following words at the end of the first sentence: "unless reviewed by the prescribing individual practitioner."b. By revising the parenthetical item in the second sentence to read as follows: "(for a prescription for a uniformly maintained, readily retrievable record, such as medication records, which indicates the date, quantity, and name of the dispensing pharmacist for each prescription refill, and the total number of refills for each prescription)."

45. By renumbering § 306.23 to be § 306.24, renumbering § 306.24 to be § 306.25, and adding a new section to read as follows: § 306.23 Partial filling of prescriptions. The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible, provided that: (a) Each partial filling is recorded in the same manner as a refilling. (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

46. By amending § 306.32 as follows: a. In paragraph (a) by deleting the word "distribution" and substituting the word "dispensing", by deleting immediately after the word "pharmacists" where it first appears the words "as defined in § 306.02(d)," and by deleting the word "directly."b. In paragraph (b) by adding the word "controlled" between the words "such" and "substance", by adding the word "controlled" between the words "other" and "controlled", by deleting the words "scheduled as a controlled substance immediately after the words "other such controlled substance," the words "more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance," and by deleting the word "distributed" and substituting the word "dispensing," by deleting the words "listed in schedule V (other than by prescription)" and substituting the words "under this section", and by deleting the word "distributed" and substituting the word "dispensed".

47. By amending § 307.11 by deleting the word "dispensing" in paragraph (n) (1) and substituting the word "distribution".

48. By amending § 307.12 by deleting the title and entire section and substituting the following new section: § 307.12 Distribution by pharmacy to individual practitioners.

(a) A pharmacy which is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to an individual or institutional practitioner for the purpose of general dispensing to his or its patients: Provided, That: (1) The individual or institutional practitioner is registered under the Act to dispense the controlled substance to be distributed to him; (2) The distribution is recorded by the pharmacy in accordance with § 304.24(e) of this chapter and by the individual or institutional practitioner in accordance with § 304.24(c) of this chapter; (3) If the substance is listed in schedule I or II, an order form is used as required in Part 305 of this chapter; and (4) The total quantity of all controlled substances distributed by the pharmacy pursuant to this section and pursuant to § 307.11 during the 12-month period ending on the day which the pharmacy is registered to dispense does not exceed 5 percent of the total quantity of all controlled substances distributed and dispensed by the pharmacy during the 12-month period ending on the day of registration.

49. In any sentence or rule of this paragraph which the pharmacy is registered to dispense, the pharmacy has reason to believe that the total quantity which will be distributed by it pursuant to this section and pursuant to § 307.11 will exceed 5 percent of the total quantity of all controlled substances distributed and dispensed by it during any 12-month period, the pharmacy shall obtain a registration to distribute controlled substances.

(a) As an incident to a distribution under this section, a pharmacist, manufacturer (without being registered to manufacture) an aqueous or oleaginous solution containing a narcotic controlled substance in a proportion not exceeding 90 percent of the complete solution.

(b) This section does not permit a pharmacy to distribute (without being
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section 201(g) of the Act (21 U.S.C. 811 (g)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exception which has been accepted for filing.

52. By amending § 308.31 as follows:
   a. By deleting paragraph (c) and substituting the following new paragraph:
      (c) Within a reasonable period of time after the receipt of an application for an exception under this section, the Director shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefor. The Director need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If accepted for filing, the Director shall publish in the FEDERAL REGISTER general notice of his proposed rule making in granting or denying the application. Such notice shall include a reference to the rule, the authority under which the rule is proposed, a statement of the proposed rule granting or denying an exception, and, in the discretion of the Director, a summary of the subjects and issues involved. The Director shall permit any interested persons to file written comments on or objections to the proposal. The Director shall publish in the FEDERAL REGISTER his final order on the application, which shall set forth the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Director finds that conditions of public health or safety necessitate an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.
   b. By adding a new paragraph (d) as follows:
      (d) The Director may at any time revoke any exception granted pursuant to section 201(g) of the Act (21 U.S.C. 811 (g)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exception which has been accepted for filing.

53. By amending § 308.32 by adding the words "and § 301.74(d) of this chapter" after the parenthetical unit "(21 U.S.C. 825, 827(f), 827-9, 852-4)" in both paragraph (a) and paragraph (b) of this section.

54. By amending § 308.45 by deleting the first sentence and substituting the following: "If requested by any interested person after proceedings are initiated pursuant to § 308.45, the Director shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)."

55. By amending § 308.45 by redesignating paragraph (b) as paragraph "(c)" and paragraph (c) as "(d)" paragraph (d) as "(e)" and adding a new paragraph (b) to read as follows:
   (b) A single registration to engage in any group of independent activities may be issued under one section 308.45 if such activities are listed in the schedules authorized in that section. A person registered to conduct research with controlled substances listed in schedule I may conduct research with any substance listed in schedule I for which he has filed and has approved a research protocol.

56. By amending § 311.26 by adding immediately after the words "official" the words "or agency", adding after the word "Navy" the words "Marine Corps", and by adding after the word "who" the words "or which".

57. By amending § 311.27 by adding after the words "that section" at the end of the section the words "or Article".

58. By amending § 311.27 by adding after the words "that section" at the end of the section the words "or Article".

59. By amending § 311.28 by deleting at the end of paragraph (a) (i) the words "the "name, address, and prescription number of the pharmacy or practitioner who dispensed the substance and substituting the words "the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any.".

60. By amending § 311.31 by deleting from the end of paragraph (a) the words "registration certificate is issued by the Director" and substituting the words "registration certificate is issued by the Department of Justice, Bureau of Narcotic Affairs, to each such person who is authorized to sign applications under this paragraph and who shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant."
63. By amending § 311.42 as follows:

a. By adding immediately after the words "on the face of a claim" at the end of the third sentence of paragraph (a) the words "in accordance with § 301.54 of this chapter.";

b. By adding between the fifth and sixth sentences of paragraph (a) the following sentence: "Any such person may participate in the hearing by filing a notice of appearance in accordance with § 301.54 of this chapter."

64. By adding four new sections as follows:

**MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION**

§ 311.61 Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, 400 7th St., S.W., Washington, D.C. 20537. The letter shall contain the registrant's name, address, registration number, and the substances and/or schedules to be added to his registration, and shall be signed by the same person who signed the most recent application for registration or reregistration. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.

§ 311.62 Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the Director promptly of such fact. In the event of a change in the name or address of the person, the registrant may apply for a new Certificate of Registration in advance of the effective date of such change by filing an application and paying the appropriate fee in the same manner as an application for new registration. The application shall be handled in the same manner as an application for registration.

§ 311.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Director may specify and designate and then only pursuant to his written consent.

§ 311.64 Termination of provisional registration.

The registration of any person who is provisionally registered under section 702(a) of the Act (21 U.S.C. 822 note) and who have not been assigned a date for registration by August 31, 1971, shall terminate on October 1, 1971.