RULES AND REGULATIONS

(Sec. 512(i), 82 Stat. 347; 21 T.S.C. 3609(b)(1))

C. D. VAN HOUWELING,
Director,
Bureau of Veterinary Medicine.

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Chapter II—Bureau of Narcotics and Dangerous Drugs, Department of Justice

IMPLEMENTATION OF COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970


In response, a substantial number of comments were received from members of the disclosures Institute of the Pharmaceutical Manufacturers Association, the National Association of Pharmaceutical Manufacturers, the National Association of Boards of Pharmacy, the American Society of Hospital Pharmacists, the American Hospital Association, the National Association of Retail Drugists, the American Pharmaceutical Association, the National Association of Chain Drug Stores, the National Wholesale Drugists' Association, and from various individuals, corporations, and institutions.

The comments and objections centered on five areas of the proposals: (1) Changes in registration requirements for interns, residents, and foreign-trained physicians; (2) security requirements; (3) refill prescriptions for schedule III and IV substances; (4) distributions by pharmacies to practitioners; and (5) modification and termination of registrations.

1. Changes in registration requirements for interns, residents and foreign physicians (§ 301.24(c)). Numerous comments and objections were received from hospitals, physicians, and national professional organizations. The American Medical Association, the American Society of Hospital Pharmacists, and the American Hospital Association recommended adoption of these regulations. The majority of the comments received were valid and modifications were subsequently incorporated into the regulations. Other comments resulted from misinterpretation of the proposed regulations. One major point of misinterpretation which the Director wishes to clarify is that § 301.24(c) is an optional section. Hospitals may either adopt this system or require staff interns, residents, and foreign-trained physicians to register with the Bureau of Narcotics and Dangerous Drugs in their own names. Physicians who have their own BNNQ registration numbers may not avail themselves of this alternative method for prescribing controlled substances, but must use their own BNNQ registration numbers.

The Director suggests that State hospital and medical associations contact the appropriate officials in their respective States to seek changes on the authority of interns, residents, or foreign-trained physicians to prescribe, dispense and administer controlled drugs within the State. Subsections 2(a) generally satisfy the requirement that the hospital or other institution have verified the authority of the intern, resident, or foreign-trained physician to so prescribe, dispense and administer any controlled substance.

2. Security requirements (§§ 301.71—301.74). Comments were received from numerous sources, and several meetings were held with representatives of the Pharmaceutical Manufacturers Association, the National Wholesale Drugists Association, and the National Association of Chain Drug Stores. The comments reflected apparent confusion over the Bureau's intent in promulgating security regulations. Sections 301.72 and 301.73 prescribe minimum standards which must be satisfied by the registrant (other than practitioners), based on the Bureau finds in an individual situation that, because of special factors outlined in § 301.71(b), deviation from the standards would not result in a serious security hazard. The Director should understand that deviations are within the discretion of the Bureau and will be made on a case-by-case basis; an exception made for one registrant may not be available in another situation, if conditions are identical. In order to reduce the confusion, §§ 301.71, 301.72, 301.73, and 301.74 have been substantially restructured. In addition, many specific comments have been incorporated in the final order.

The Director wishes to point out that detailed guidelines will be prepared to implement these regulations and will cover many of the comments raised during the discussions. The Bureau is favorably disposed toward two types of security controls not expressly covered by the regulations: (a) Automatic storage and retrieval systems and special pharmacy storage areas in drug warehouses. The Bureau will accept recommendations for such systems, evaluated in individual cases to determine whether they substantially comply with the regulations. Although not part of the proposed order, security regulations for the practice of pharmacy have drawn many comments recently because of the transfer of amphetamine and methamphetamine products to schedule II. Many individuals and associations have objected to the requirement that these products be stored in a "substantially constructed, securely locked cabinet" as provided in § 301.75(a). The Director has considered these and the special reasons for the existing regulations should not be changed. There are three basic forms of theft in pharmacies or physicians' offices: robbery, burglary, and pilferage. The first can only be impeded through a safe and alarm system, as was first proposed in March 1971 by the Bureau; such a system would also effectively prevent burglaries and pilferage from open}

stock by employees, salesmen, patients, and other persons having access to the general storage area. The representations of the practitioners' objections to the proposal of a safe and alarm system and the proposal was dropped with the understanding that the locked cabinet provided a sufficient barrier to theft, the cost of which was more proportional to its benefits. It should be remembered that every bottle containing a schedule II drug will bear a label with a II at the top of the label or on the print on the label. (See § 302.64 of the regulations.) This labeling size is smaller than print size requested by some pharmacy associations in the year of London, with these labels will not provide any additional protection from burglary or pilferage than placing them in a locked cabinet. For these reasons, the Director has concluded that, subject to the tentative dates set forth at the end of this order, all controlled substances listed in schedule-II must be stored in a substantially constructed, securely locked cabinet.

3. Refilling schedules III and IV prescriptions (§ 306.22). It was proposed that the words "unless renewed by the practitioner" be added to the end of the section of § 306.22 of the American Pharmaceutical Association correctly pointed out the confusion created in the light of the final order of the primitive. Furthermore, the manner in which a prescription must be renewed. Therefore, this proposal will not be made final. In addition, the requirements for medication records were not fully specified and have now been completely set forth. The Director wishes to emphasize that medication records are acceptable only if they are in fact "readily retrievable"; a prescription leg will not be satisfactory but a record showing the patient's name, each prescription number, and the information required for each refill of the prescription will generally be satisfactory.

4. Distributions by pharmacies to practitioners. This proposal generated significant discussion particularly from the National Association of Retail Drugists and the American Pharmaceutical Association. Serious questions were raised concerning the practicality of the proposal "5 percent" test to determine when registration as a distributor is required. The Director recognizes that pharmacies and other dispensers perform a vital and necessary service function of providing limited supplies of drugs, including controlled substances, to other practitioners. Section 307.11 was originally issued to legalize this practice in emergency situations. Section 307.12 was proposed to extend the current authorization to non-emergency situations.

Section 303(d) of the Controlled Substances Act authorized the Bureau to waive registrant requirements for certain distributors where consistent with public health and safety. The Director finds that at this time the limits of the regulation is limited.

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a practitioner for the purpose of accommodating and servicing another practitioner, without the supplying practitioner's being registered as a distributor, is consistent with public health and safety. Sections 307.11 and 307.12 (as proposed) have been merged to permit these distributions.

The Director believes that any practitioner who is genuinely engaged in distributing controlled substances solely for the purpose of servicing them will not distribute even as much as 5 percent of his total volume of controlled substances. Stated differently, to be a practitioner distributor over 5 percent of his controlled substances, he is probably engaged in a significant wholesaling business and should register as a distributor. By permitting a practitioner to distribute up to 5 percent of his controlled drugs, without registering as a distributor, the Bureau is not encouraging pharmacies and other practitioners to expand their distribution activities. The focus of the Bureau remains fixed on the nature of the transaction, e.g., providing a service to the other practitioners, rather than engaging in the exchange of drugs. Distribution privileges granted by the new § 307.11 are not abused, the Director will reconsider his finding regarding the public health and safety and may remove distribution privileges.

In regard to records of distributions to be kept by practitioners, the Bureau will accept either of two systems: Invoices, order forms, and other documents showing distribution by a person may be stamped and filed in the same manner as prescriptions (although the records must clearly show that this was a distribution, not a dispensing or prescription) or the documents may be filed separately from the prescription or other dispensing records.

5. Modification and termination of registrations (§§ 301.61–62; §§ 511.61–62). The Pharmaceutical Manufacturers Association requested a special provision to be made to prevent automatic termination of a registration when there is a change in address but no change in location. The Director concurs in the need for such a provision and the Bureau will propose a change to accomplish it in the near future.

Some other objections and comments were received, the majority of which were valid and incorporated into the amendments. Others resulted from a misinterpretation of the language of the proposed regulations, and frequently the language was revised to clarify the intent of the Bureau. In a few cases, not discussed here the Director did not accept the position of the party.

The Director has instructed the Office of Chief Counsel of the Bureau to reply to each person who filed comments and respond fully to his comments.

Therefore, under the authority vested in the Attorney General by sections 201 (a), 201 (g), 201(d), 301, 302(1), 304, 305, 306(d), 307, 308, 501(b), 505, 511, 513, 704(a), 704(b), 706, 707(b), 1008(d), 1008(e), and 1015 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and redelegated to the Director, Bureau of Narcotics and Dangerous Drugs, by § 0.100 of Title 28 of the Code of Federal Regulations, the Director hereby orders that Parts 301, 302, 303, 304, 305, and 311 of Title 21 of the Code of Federal Regulations be amended as follows:

PART 301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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 its" immediately after the word "his" in paragraph (a)(2), and by adding the words "if an individual" or "officer (or an agency)" immediately after the word "superior" in paragraph (b).

2. By amending § 301.22 as follows: a. By deleting the word "eight" from paragraph (a); b. By deleting paragraphs (a)(3) and (4), replacing them with the following, and redesignating paragraph (a)(3) as (a)(5), (6), (7), and (8) as (a)(7), (8), and (10):

(3) Dispensing controlled substances listed in schedules II through V;
(4) Conducting research (other than research described in subparagraph (6) of this paragraph) with controlled substances listed in schedules II through V;
(5) Conducting instructional activities with controlled substances listed in schedules II through V;
(6) Conducting research with narcotic drugs listed in schedules II through V for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addiction rehabilitation program pursuant to a Notice of Claimed Investigational Exemption for a New Drug approved by the Food and Drug Administration;

c. By adding the words "preclinical research (including quality)" immediately after the words "after the words "clinical and analysis and in paragraph (b)(2);

d. 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);

e. By adding the words "or authorized" immediately after the words "A person registered or authorized to conduct research with such class of substances (in paragraph (a)(3) of this section) with controlled substances listed in schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 301.26, and to conduct instructional activities with controlled substances;

f. By adding a new paragraph (b)(6) to read as follows:

(6) A person registered to dispense controlled substances listed in schedules II through V shall be authorized to conduct research (other than research described in paragraph (a)(5) of this section) and to conduct instructional activities with those substances,

g. By deleting paragraph (d) and replacing it with the following:

(2) A person registered or authorized to conduct research (other than research described in paragraph (a)(3) of this section) with controlled substances listed in schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 301.26, and to conduct instructional activities with controlled substances;

h. By deleting paragraph (a) and replacing it with the following:

(1) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. 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 had approved a research protocol.

3. By amending § 301.25 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 § 301.24 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 such agent or employee is acting in the usual course of his business or employment.

(b) An individual practitioner, as defined in § 304.62 of this chapter (other than an intern, resident, foreign-trained physician, or physician on the staff of a Veterans Administration facility), 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 practitioners who may be 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.)

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(a) An individual practitioner, as defined in § 304.02 of this chapter, who is an intern, resident, or foreign-trained physician or physician on the staff of a Veterans Administration facility, may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom he is employed in lieu of being registered himself, 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 verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within 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 registration and designates a specific internal code number for each intern, resident, or foreign physician so authorized. The code number shall consist of letters, numbers, or a combination thereof and shall be a suffix to the institution's BNDN registration number, preceded by a hyphen (e.g., AFO153456-10 or AFO153456-A123); and

(6) The correspondence that the individual practitioner is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

5. By amending § 301.25 by substituting "but shall state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and for "but shall use" in paragraph (a), and by adding the following sentence at the end of paragraph (a): "The service identification number for a Public Health Service employee is his Social Security identification number.

6. By amending § 301.28 by adding the words "Marine Corps" after the word "Navy" in paragraph (a) (1). By amending § 301.32 as follows:

a. By deleting paragraphs (a) (2), (3), (4), and (5) and replacing these subparagraphs with the following, and redesignating paragraph (a) (6) as (a) (5):

(2) To conduct instructional activities with controlled substances listed in schedules II through V, he shall apply on BND Form 224;

(3) To conduct instructional activities with controlled substances listed in schedules II through V, he shall apply on BND Form 224;

(4) To conduct research with controlled substances listed in schedules II through V, he shall apply on BND Form 225;

(5) To conduct research with controlled substances listed in schedules II through V, as described in § 301.22(a)(6), he shall apply on BND Form 225.

6. By deleting § 301.61 and replacing it with the following:

§ 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 20853, Central Station, Washington, D.C. 20030. 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 in accordance with § 301.22(d). If the registrant is seeking 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, 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.

10. By adding a new section as follows:

§ 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 has not been assigned a date for registration by August 1, 1971, shall terminate on October 1, 1971.

11. By deleting § 301.71 and replacing it with the following:

§ 301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine if a registrant has provided effective controls against diversion, the Director shall use the security requirements set forth in §§ 301.72-301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 301.72, 301.73 and 301.75 may be used in lieu of the materials and construction described in those sections.

(b) Any individual compliance with the standards set forth in §§ 301.72-301.76 may be deemed sufficient by the Director after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Director may consider any of the following factors, as he may deem relevant to the need for strict compliance with security requirements:
(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type of form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervisory transmission lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

Where physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the registrant may adjust physical security controls within the requirements set forth in §§ 301.72-301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or as a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

An registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 301.72-301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Regional Director in the region in which the registrant resides, or to the Compliance Investigations Division, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(4) Physical security controls of locations regulated under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1990 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 301.72, 301.73 and 301.75 of this chapter, if the facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Bureau, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 301.72, 301.73 and 301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Bureau.

12. By adding two new sections as follows:

§ 301.72 Physical security controls for nonpractitioners: storage areas.

(a) Schedules I and II. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in schedule I or II shall be stored in one of the following secure storage areas:

1. Wiere small quantities permit, a safe:

(i) Which safe has an Underwriters' Laboratories Burglary Rating of T-20, E or better, or the equivalent of such a safe;

(ii) 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; and

(iii) 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 station 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 Director may approve.

2. A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system:

(a) A vault constructed after September 1, 1971:

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 5/8-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

2. The 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 5/8-inch or with a 2-hour fire rating or the equivalent;

3. Which vault, if operations require it to remain open for frequent access, is equipped with a "day-cage" which is self-contained and self-locating, 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 station 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, holdup 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 lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or other device designated to detect a new entry as may be approved by the Bureau.

(b) Schedules III, IV, and V. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in schedules III, IV, and V shall be stored in one of the following secure storage areas:

1. Where small quantities permit, a safe which complies with the requirements set forth in paragraph (a) (1) of this section;

2. A vault which complies with the requirements set forth in either paragraph (a) (2) or (3) of this section;

3. A building or area located within a building, which building or area:

(a) Has walls or perimeter fences of sufficient height and construction to provide security from burglary;

(b) Has substantial doors which may be securely locked during nonworking hours by a multiple-position combination or key lock;

(c) Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station 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; and

4. In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(c) Multiple storage areas. Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to a minimum number of specifically authorized...
employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

§ 301.73 Physical security controls for nonpractitioners: Manufacturing areas.

All manufacturing activities (including processing, packaging, and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

(a) All areas in which controlled substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous manufacturing operation should not be interrupted), the processing area or vaults, tanks, bins or bulk containers containing such substances shall be securely locked and secured for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or to state or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as the "security force," and wherein limited access may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as "security force" in the area may be engaged in the particular manufacturing operation being conducted: Provided, That he is able to provide continuous surveillance of the area in question and unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing area shall be under the observation of only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

13. By amending §301.74 as follows:

(a) By adding a new sentence at the end of paragraph (c) 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 "Schedules II through V" and by adding a new sentence at the end of paragraph (d) to read as follows: "For purposes of this paragraph, the term 'customer' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person;"

(c) By adding a new paragraph (e) to read as follows:

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security against theft and diversion losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security against theft and diversion losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in §301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against theft or in-transit losses.

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 §302.03 by deleting paragraph (g) of that section.

16. By adding a new section as follows:

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

(a) The symbol requirements of §§302.03-302.06 apply to every commercial container, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States, as defined in §311.02 of this chapter.

(b) The symbol requirements of §§302.03-302.06 do not apply to any commercial containers containing, or 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 316 of this chapter" and replacing these words with the words "in accordance with §303.34" at the end of the third sentence of paragraph (e), and by adding a new sentence at the end of paragraph (d) 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 "it" for the word "as" in the third sentence of paragraph (d).

(c) By revising paragraph (e) (2) to read as follows:

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

(d) By adding the words "or II" immediately after the words "schedules I;" and by deleting the number "(3)" immediately after the number "301.22(b)," in paragraph (a) (3).

19. By amending §303.34 by adding at the end of paragraph (a) the following sentence: "Any interested person who desires a hearing on the determination of an aggregate production amount shall, within the time prescribed in §303.11(e), file with the Director a written request for a hearing in the form prescribed in §316.47 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 such activities without being registered to conduct those activities, either pursuant to §301.22(b) of this chapter or pursuant to §§307.11-307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities (e.g., when a registered manufacturer conducts chemical analysis, he shall maintain the records and inventories required of chemical analysis)."
21. By amending § 304.14 by deleting the words “in manufacturing, distributing, or dispensing” and substituting the word “manufacturing” in the fifth sentence of paragraph (d) of this section and substituting the words “manufacturing” in the first sentence of paragraph (d) of this section.

22. By amending § 304.15 by deleting the words “Each registered manufacturer” at the beginning of the paragraph and substituting the words “Each person registered or authorized (by § 301.22(b), § 307.11, or § 307.15 of this chapter)” to produce 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 307.11–307.14 of this chapter)” to disperse controlled substances.

24. By amending § 304.17 by adding the words “authorized by §§ 301.22(b) or 307.11–307.14 of this chapter” immediately after the words “Each person registered” at the beginning of the sentence.

25. By amending § 304.17 by deleting the words “Each registered importer or exporter” in the first sentence of the paragraph and substituting the words “Each person registered or authorized (by §§ 301.22(b) or 307.11–307.14 of this chapter)” to import or export controlled substances, and by deleting the words “Each registered importer and exporter” in the second sentence of the paragraph and substituting the words “Each person registered or authorized (by §§ 301.22(b) or 307.11–307.14 of this chapter)”.

26. By amending § 304.19 as follows:

a. By deleting the words “Each analytical laboratory registered” at the beginning of the paragraph and substituting the words “Each person registered or authorized (by §§ 301.22(b) or 307.11–307.14 of this chapter)”.

b. By deleting the word “his” in the first sentence of the section and substituting the word “his”.

c. By deleting the words “the 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 evidence materials for analysis.”

27. By amending § 304.22 as follows:

a. By deleting the words “Each registered manufacturer” at the beginning of the paragraph and substituting the words “Each person registered or authorized (by §§ 301.22(b) or 307.11–307.14 of this chapter)” to manufacture controlled substances.

b. By revising paragraph (b) (5) to read as follows: “The number of units of finished forms and/or commercial containers in commercial import (under 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 § 304.23 as follows:

a. By deleting the words “Each registered distributor” and substituting the words “Each person registered or authorized (by §§ 301.22(b) or § 307.11–307.14 of this chapter)” to distribute controlled substances.”

b. By revising paragraph (d) 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; and

(2) The first sentence of paragraph (d).

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 paragraph.

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 “of this chapter” at the beginning of the paragraph and substituting 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 “evidence 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 I, II, and III sold to practitioners” in the first sentence of paragraph (d) and substituting the words “listed in schedule III sold to dispensers.”

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 § 309.35 of 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 words “exporter,” in the first sentence of paragraph (b).

c. By deleting the words “fourth quarter” 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).

PART 305—ORDER FORMS

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 any, printed thereon. In the case of order forms issued to a person registered to conduct chemical activities 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.”

36. By amending § 305.06 by deleting the last sentence of paragraph (b).

37. 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).


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.”

PART 306—PRESCRIPTIONS

40. By amending § 306.02 by revising the definition of register in paragraph (f) as follows:

(1) The terms “register” and “registered” refer to registration required and permitted by section 305 of the Act (31 U.S.C. 622).

41. By amending § 306.03 by deleting the number “301.25” in paragraph
(a) (2) and substituting the numbers "§301.24(e) and 301.25.”

42. By amending §306.05 by designating the existing paragraph as paragraph (a) and by adding two new paragraphs as follows:

(b) An intern, resident, or foreign-trained physician, or physician on the staff of a Veterans Administration facility, exempted from registration under §301.24(e) shall be deemed to be registered immediately after the word "pharmacists" that it first appears the words "as defined in §306.08(d))." and by deleting the word "direct"

48. By amending §306.32 as follows:

b. In paragraph (b) by adding the word "controlled" between the words "such" and "substance", by adding the words "such between the words "other") and "controlled", by deleting the words "listed in schedule V", by adding immediately after the words "other such controlled substance," the words "or more than 24 dosage units of any other such controlled substance," and by deleting the word "distributed" and substituting the word "dispensed.

c. In paragraph (c) by deleting the words "listed in schedule V" and substituting the words "under this section".

d. In paragraph (a) by deleting the word "distributions" and substituting the word "dispensed", 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.

PART 307—MISCELLANEOUS

49. By amending §307.11 by deleting the title and entire section and substituting the following new section:

§307.11 Distribution by dispenser to another practitioner.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or her patients: Provided, That:

(1) The practitioner to whom the controlled substance is delivered is registered under the Act to dispense that controlled substance;

(2) The distribution is recorded by the distributing practitioner in accordance with §304.24(a) of this chapter and by the receiving 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 subchapter;

(4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during the 12-month period in which the practitioner is registered to dispense that controlled substance does not exceed the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the 12-month period.

(b) If, at any time during the 12-month period during which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section will exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by him during the 12-month period, the practitioner shall obtain a registration to distribute controlled substances.

50. By amending §307.12 to read as follows:

§307.12 Manufacture and distribution of narcotic solutions and compounds by a pharmacist.

As an incident to a distribution under §307.11, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or a saleable solid form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.

51. By amending §307.15 by adding to the end of this section the following sentence: “Any person not required to register pursuant to sections 302(c) or 109(b)(1) of the Act (21 U.S.C. 823(c) or 827(b)(1)) shall be exempt from maintaining the records required by this section.”

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

52. By amending §308.02 by deleting the word "issued" in paragraph (b), and substituting the word "issuable" in paragraph (b).

53. By amending §308.51 as follows:

(a) By deleting paragraph (b) and substituting the following new paragraph:

(b) An application for an exclusion under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The name of the substance for which exclusion is sought; and

(3) The complete quantitative composition of the substance.

(b) By adding a new paragraph (c) as follows:

(c) Within a reasonable period of time after the receipt of an application for an exclusion 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.

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application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exclusion, or denying an exclusion when he finds that the substance may not, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 311), lawfully be sold over-the-counter without a prescription, or that the substance is non-narcotic, and, in the discretion of the Director, a summary of the subjects and issues involved. The Director shall permit any interested person to file written comments or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made. After consideration of the application and any comments on or objections to his proposed rule making, the Director shall issue and 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. This order shall specify the date on which it shall take effect, and the provisions of the Act which shall be in force on 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 exclusion granted pursuant to section 202(d) of the Act (21 U.S.C. 812) by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

54. By amending § 308.33 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 rejection 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 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 be a reference to the legal 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 person to file written comments or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made. After consideration of the application and any comments on or objections to his proposed rule making, the Director shall issue and 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. This order shall specify the date on which it shall take effect, and the provisions of the Act which shall be in force on 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 exclusion granted pursuant to section 202(d) of the Act (21 U.S.C. 812) by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

55. By amending § 308.33 by adding the words “and of § 301.74(d) of this chapter” after the parenthetical unit “(21 U.S.C. 823, 825–8, 833)” in both paragraphs (a) and (b) of section 308.33.

56. By amending § 308.42 by deleting the first sentence and substituting the following:

“If requested by any interested person after proceedings are initiated pursuant to § 308.44, 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 revocation of a rule issued pursuant to section 201(a) of the Act (21 U.S.C. 811(a)).”

57. By amending § 308.45 by redesignating paragraph (b) as paragraph “(c)”, paragraph (e) as “(d)”, paragraph (d) as “(e)”, and adding a new paragraph (b) to read as follows:

(b) Any interested person desiring to participate in a hearing pursuant to § 308.41 shall, within 10 days after the date of publication of the notice of hearing in the Federal Register, file with the Director a written notice of his intention to participate in such hearing in the form prescribed in § 316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall alone be deemed to be a notice of appearance.

PART 311—REGISTRATION OF IMPORTERS AND EXPORTERS OF CONTROLLED SUBSTANCES

58. By amending § 311.22 by deleting paragraph (b) and replacing it with the following:

(b) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances in schedule I may conduct research with any substance listed in schedule I for which he has filed and has approved a research protocol.

59. By amending § 311.24 by adding immediately after the words “official” the words “or agency”, adding after the word “matters” the words “or matters or activities”, and by adding after the word “who” the words “or which”.

60. By amending § 311.25 by adding after the words “that section” at the end of the section the words “or Article 6.”

61. By amending § 311.27 by adding after the words “that section” at the end of the section the words “or Article 6.”

62. By amending § 311.28 by deleting at the end of paragraph (a) (2) (II) the words “the name, address, and prescription number of the pharmacy or practitioner who dispensed the substance” and adding after the words “the name of the pharmacy or practitioner who dispensed the substance and the prescription number, if any.”

63. By amending § 311.31 by deleting from the end of paragraph (a) the words “a registration certificate is issued by the Director” and substituting the words “a Certificate of Registration is issued by the Director to such person.”

64. By amending § 311.32 by adding at the end of paragraph (l) the following sentences: “An applicant may authorize one or more individuals, who would otherwise be authorized to do so, to file applications for the applicant by filing with the Registration Branch of the Bureau a power of attorney on BND Form 251a 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 signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.”

65. By amending § 311.42 as follows:

a. By adding immediately after the words “on the application” at the end of the third sentence of paragraph (a) the words “in accordance with § 301.64 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 § 301.64 of this chapter.”

66. 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, Food and Drug Administration, Drug Enforcement Administration, Department of Justice, Post Office Box 38083, Central Station, Washington, D.C. 20008. The letter shall contain the name and address of the person to whom the modification is desired, the name and number of the registration, the substance or substances and/or schedules to be added to his registration, and shall be signed in accordance with § 311.31(d). Notice shall be required to be given to the interested parties. 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 whose registration has ceased to be effective shall be notified by certified mail that his registration shall terminate unless he shall first file with the Director such application as may be required to effect a change in name or address. Failure to file such application shall result in the termination of the registration of such person.

§ 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 specifically 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.

Effective dates. This order is effective upon publication in the Federal Register (8-21-71), except that the security regulations for nonpractitioners set forth in §§ 301.72 and 301.73 shall not take effect until March 1, 1972. In addition, the Director hereby announces that amphetamine and methamphetamine products listed in schedule II shall not be stored by practitioners in the locked cabinet, as required in § 301.75(a), until January 1, 1972. The Director realizes that because of the transfer of amphetamine and methamphetamine products listed in schedule II, and contemplated action by the Federal Food and Drug Administration, it is difficult to foresee future requirements for these substances. Consequently, it is difficult to predict the needed secure storage facilities for these substances. It is hoped that by January 1, 1972, the situation will be clarified sufficiently to implement security controls at the practitioner level, and to plan controls for the nonpractitioner levels. In the event that the situation remains unclear, the Director will receive suggestions for delay in implementing security controls.
The Director continues to invite comments on all of the rules and regulations promulgated under the Comprehensive Drug Abuse Prevention and Control Act of 1970 and will consider such comments for amendatory purposes.

Dated: September 13, 1971.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

Title 41—PUBLIC CONTRACTS AND PROPERTY MANAGEMENT

Chapter 5A—Federal Supply Service, General Services Administration

PART 5A-2—PROCUREMENT BY FORMAL ADVERTISING

Notification of Unsuccessful Lower Bidders of Rejection of Their Bids

The table of contents for Part 5A-2 is amended to delete §§ 5A-2.408-1 and 5A-2.409-2, and to add the following entries:

Sec. 5A-2.408-70 Notification to particular unsuccessful bidder.

5A-2.408-71 Restriction on disclosure of inspection or test data.

Subpart 5A-2.4—Opening of Bids and Award of Contract

1. Section 5A-2.406-70 is added as follows:

§ 5A-2.408-70 Notification to particular unsuccessful bidder.

(a) In any case where award is not made to the apparent low bidder(s) as originally listed on the bid abstract, the bidder(s) shall be notified and given the reason why the bid was not accepted. This includes cases in which a late bid properly considered, or a bid which originally contained a mistake but was permitted to be corrected, displaced a bid which was low at time of public opening. In addition, notification shall be given to each unsuccessful bidder who, by reason of his position on the bid abstract and by actions on the part of the contracting officer after bid opening, may have assumed, or been led to assume, that he would receive the award. Examples of such actions are:

(1) Request for extension of bid acceptance time;
(2) Request for verification or clarification of other aspects of bid;
(3) Plant facility inspections; and
(4) Financial responsibility determinations.

(b) Notification to unsuccessful lower bidders of the rejection of their bids shall be in writing and shall be prepared and submitted for signature and dispatch at the same time that the related awards are submitted for the contracting officer's signature and release.

2. Section 5A-2.408-71 is added as follows:

§ 5A-2.408-71 Restriction on disclosure of inspection or test data.

(a) No information regarding inspection or test data shall be disclosed to any person except as provided in this subsection. This includes information obtained from inspection or test reports whether prepared by Government inspection personnel or by an outside inspection or testing agency utilized by the Government or furnished by a contractor under a Quality Assurance Agreement.

(b) Prior to award, no information regarding inspection or test data shall be disclosed to any bidder or individual except Government officials or employees required to have access to such information in connection with bid evaluation and determination of award.

(c) The contracting officer shall (1) upon request, or in the notification regarding rejection of a bid, inform a bidder concerning the results of tests on the products offered by the bidder and (2) furnish such information to other officials or employees of the Government who have need to know such information.

(d) If an unsuccessful bidder requests information regarding the merits or quality of a contractor's product and the competitor was the successful bidder, information shall be limited solely to the statement, if applicable, that adequate inspection or testing has shown that the successful bidder's product met the requirements of the invitation for bids. If the competitor was also unsuccessful, information shall be limited to a statement that the bid was not accepted; any indication as to the merits or quality of the competitor's product shall be avoided.

Title 49—TRANSPORTATION

Chapter X—Interstate Commerce Commission

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[Ex Parte No. MC-30 (Sub-File No. 1)]

PART 1048—COMMERCIAL ZONES

Cincinnati, Ohio, Commercial Zone

Order on further consideration. At a session of the Interstate Commerce Commission, Review Board No. 3, Members Bilodeau, Beddoes, and Grossman, held at its office in Washington, D.C., on the 24th day of August 1971. It appearing, that on May 29, 1971, the Commission, Review Board No. 3, made and filed its report and order on