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VOLUME 36 • NUMBER 26

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Pages 2549–2586

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Agricultural Research Service
Atomic Energy Commission
Civil Aeronautics Board
Consumer and Marketing Service
Engineers Corps
Federal Aviation Administration
Federal Communications Commission
Federal Maritime Commission
Federal Power Commission
Food and Drug Administration
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Immigration and Naturalization Service
Interim Compliance Panel (Coal Mine Health and Safety)
Internal Revenue Service
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Packers and Stockyards Administration
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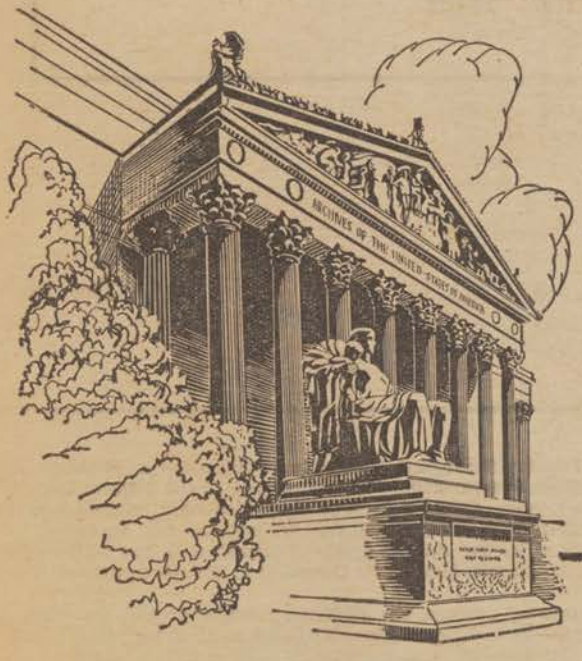

THE NATIONAL ARCHIVES OF THE UNITED STATES
LITTERA SCRIPTA MANET
* 1934 *

Volume 83

UNITED STATES STATUTES AT LARGE

91st Congress, 1st Session
1969

Contains laws and concurrent resolutions enacted by the Congress during 1969, reorganization plan, recommendations of the President, and Presidential proclamations. Also included are: numerical listings of bills enacted into public and private law, a guide to the legislative history of bills enacted into public law, tables of prior laws affected, and a subject index.

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Title 7—AGRICULTURE

Chapter IX—Consumer and Marketing Service (Marketing Agreements and Orders; Fruits, Vegetables, Nuts), Department of Agriculture

[Lemon Reg. 466]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

§ 910.766 Lemon regulation 466.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such lemons, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice engage in public rule-making procedure, and postpone the effective date of this section until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for lemons and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such lemons; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period herein specified; and compliance with this section will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on February 2, 1971.

(b) *Order.* (1) The respective quantities of lemons grown in California and Arizona which may be handled during the period February 7, 1971, through February 13, 1971, are hereby fixed as follows:

(i) District 1: 37,000 Cartons;

(ii) District 2: 118,000 Cartons;

(iii) District 3: Unlimited.

(2) As used in this section, "handled," "District 1," "District 2," "District 3," and "carton" have the same meaning as when used in the said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: February 4, 1971.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Consumer and Marketing Service.

[FR Doc.71–1762 Filed 2–5–71;8:48 am]

Title 8—ALIENS AND NATIONALITY

Chapter I—Immigration and Naturalization Service, Department of Justice

PART 214—NONIMMIGRANT CLASSES

PART 242—PROCEEDINGS TO DETERMINE DEPORTABILITY OF ALIENS IN THE UNITED STATES: APPREHENSION, CUSTODY, HEARING, AND APPEAL

Miscellaneous Amendments

The following amendments to Chapter I of Title 8 of the Code of Federal Regulations are hereby prescribed:

Paragraph (a) of § 214.3 is amended to read as follows:

§ 214.3 Petitions for approval of schools.

(a) *Filing of petition.* A school or school system seeking approval for the attendance by nonimmigrant students under section 101(a)(15)(F) of the Act shall file petition Form I–17 with the district director having jurisdiction over the place in which the school or school system is located. Separate petitions are required for school-system schools located within the jurisdiction of different district directors. A petition by a school system shall specifically identify by name and location those schools included in the petition.

* * * * *

Paragraph (b) *Authority of special inquiry officers; appeals* of § 242.2 *Apprehension, custody, and detention* is amended by inserting the following two sentences after the existing first sentence reading as follows:

§ 242.2 Apprehension, custody, and detention.

* * * * *

(b) * * * Application for the exercise of such authority may be made to any available special inquiry officer who is stationed at the Service office which has administrative jurisdiction over the proceeding under the order to show cause or who conducts hearings there. If no such special inquiry officer is available, application may be made to any available special inquiry officer stationed in the region wherein said Service office is located. * * *

* * * * *

(Sec. 103, 66 Stat. 173; 8 U.S.C. 1103)

This order shall be effective on the date of its publication in the FEDERAL REGISTER (2–6–71). Compliance with the provisions of section 553 of title 5 of the United States Code (80 Stat. 383), as to notice of proposed rule making and delayed effective date, is unnecessary in this instance and would serve no useful purpose because the amendments prescribed by the order are clarifying in nature.

Dated: February 2, 1971.

RAYMOND F. FARRELL,
Commissioner of Immigration and Naturalization.

[FR Doc.71–1660 Filed 2–5–71;8:45 am]

Title 9—ANIMALS AND ANIMAL PRODUCTS

Chapter I—Agricultural Research Service, Department of Agriculture

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS AND POULTRY

[Docket No. 71–510]

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES

Areas Quarantined

Pursuant to provisions of the Act of May 29, 1884, as amended, the Act of February 2, 1903, as amended, the Act of March 3, 1905, as amended, the Act of September 6, 1961, and the Act of July 2, 1962 (21 U.S.C. 111–113, 114g, 115, 117, 120, 121, 123–126, 134b, 134f), Part 76, Title 9, Code of Federal Regulations, restricting the interstate movement of swine and certain products because of hog cholera and other communicable

swine diseases, is hereby amended in the following respects:

In § 76.2, paragraph (e)(3) relating to the State of Florida is amended to read:

(3) *Florida.* (i) That portion of Escambia County bounded by a line beginning at the junction of U.S. Highway 29, State Highway 95 and State Highway 10, U.S. Highway 90A; thence, following U.S. Highway 29, State Highway 95 in a northwesterly direction to State Highway 196; thence, following State Highway 196 in a westerly direction to State Highway 99; thence, following State Highway 99 in a northwesterly direction to the Perdido River; thence, following the east bank of the Perdido River in a generally southerly direction to State Highway 10, U.S. Highway 90A; thence, following State Highway 10, U.S. Highway 90A in a northeasterly direction to its junction with U.S. Highway 29, State Highway 95.

(ii) That portion of Alachua County bounded by a line beginning at the junction of State Highway 236 and U.S. Highway 41, State Highway 45; thence, following State Highway 236 in a northeasterly direction to State Highway 121; thence, following State Highway 121 in a southeasterly direction to U.S. Highway 441, State Highways 20 and 25; thence, following U.S. Highway 441, State Highways 20 and 25 in a southeasterly direction to State Highway 23; thence, following State Highway 23 in a southwesterly direction to State Highway 232; thence, following State Highway 232 in a generally northwesterly direction to U.S. Highway 41, State Highway 45; thence, following U.S. Highway 41, State Highway 45 in a northeasterly direction to its junction with State Highway 236.

(Secs. 4–7, 23 Stat. 32, as amended, secs. 1, 2, 32 Stat. 791–792, as amended, secs. 1–4, 33 Stat. 1264, 1265, as amended, sec. 1, 75 Stat. 481, secs. 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111, 112, 113, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 29 F.R. 16210, as amended)

Effective date. The foregoing amendment shall become effective upon issuance.

The amendment quarantines a portion of Alachua County, Fla., because of the existence of hog cholera. This action is deemed necessary to prevent further spread of the disease. The restrictions pertaining to the interstate movement of swine and swine products from or through quarantined areas as contained in 9 CFR Part 76, as amended, will apply to the quarantined portion of such county.

The amendment imposes certain further restrictions necessary to prevent interstate spread of hog cholera and must be made effective immediately to accomplish its purpose in the public interest. Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 2d day of February 1971.

F. J. MULHERN,
Acting Administrator,
Agricultural Research Service.

[FR Doc.71-1691 Filed 2-5-71; 8:48 am]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 27—CANNED FRUITS AND FRUIT JUICES

Canned Fruit Cocktail Identity Standard; Order Listing Slightly Sweetened Water as Optional Packing Medium

In the matter of amending the identity standard for canned fruit cocktail (21 CFR 27.40) to list slightly sweetened water as an optional packing medium:

No comments were received in response to the notice of proposed rulemaking in the above-identified matter that was published in the FEDERAL REGISTER of September 17, 1970 (35 F.R. 14557), and based on a petition filed by the California Canners and Growers, 3100 Ferry Building, San Francisco, CA 94106.

Having considered the information submitted in the petition and other relevant material, the Commissioner of Food and Drugs concludes that it will promote honesty and fair dealing in the interest of consumers to adopt the proposal.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371) and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered,* That § 27.40(c)(1) and (2) and (e)(1) be revised to read as follows:

§ 27.40 Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; identity; label statement of optional ingredients.

* * * * *

(c)(1) The optional packing media referred to in paragraph (a) of this section are as follows:

(i) Water.
(ii) Fruit juice.
(iii) Slightly sweetened water.
(iv) Light sirup.
(v) Heavy sirup.
(vi) Extra heavy sirup.
(vii) Light fruit juice sirup.
(viii) Heavy fruit juice sirup.
(ix) Extra heavy fruit juice sirup.

(2) Each of packing media in subparagraph (1) (iii), (iv), (v), and (vi) of this paragraph is prepared with water as its liquid ingredient, and each packing media in subparagraph (1) (vii), (viii), and (ix) of this paragraph is prepared with fruit juice as its liquid ingredient. Except as provided in paragraph (d)(3) of this section, each of the packing media in subparagraph (1) (iii) to (ix) in this paragraph, inclusive, is prepared with any one of the following saccharine ingredients: Sugar; invert sugar sirup; any combination of sugar or invert sugar sirup and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar or invert sugar sirup used; any combination of sugar or invert sugar sirup and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar or invert sugar sirup used; or any combination of sugar or invert sugar sirup, dextrose, and corn sirup or glucose sirup in which the weight of the solids of the dextrose used multiplied by two, added to the weight of the solids of the corn sirup or the glucose sirup used multiplied by three, is not more than the weight of the solids of the sugar or invert sugar sirup used. The respective densities of packing media in subparagraph (1) (iii) to (ix) of this paragraph, inclusive, as measured on the Brix hydrometer 15 days or more after the fruit cocktail is canned are within the range prescribed for each in the following list:

Number of packing medium:	*Brix measurement*
(1) (iii)	Less than 14°.
(1) (iv) and (vii)	14° or more but less than 18°.
(1) (v) and (viii)	18° or more but less than 22°.
(1) (vi) and (ix)	22° or more but not more than 35°.

* * * * *

(e)(1) The optional ingredients specified in paragraphs (b)(5) (ii) and (iii) and (c)(1) (i) to (ix), inclusive, of this section, are hereby designated as optional ingredients which, when used, shall be named on the label by the name whereby each is so specified.

* * * * *

Any person who will be adversely affected by the foregoing order may at any time within 30 days after its date of publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6–62, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in six copies.

Effective date. This order shall become effective 60 days after its date of publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371)

Dated: January 29, 1971.

R. E. DUGGAN,
Acting Associate Commissioner for Compliance.

[FR Doc.71-1679 Filed 2-5-71;8:47 am]

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

PART 320—DEPRESSANT AND STIMULANT DRUGS; DEFINITIONS, PROCEDURAL AND INTERPRETATIVE REGULATIONS

Chlordiazepoxide and Its Salts and Diazepam; Findings of Fact and Conclusions of Law

In the matter of listing chlordiazepoxide and its salts and diazepam as drugs subject to control under the Drug Abuse Control Amendments of 1965:

Proposed findings of fact and conclusions of law and a tentative order in this matter were published in the FEDERAL REGISTER of May 21, 1969 (34 F.R. 7968). Hoffmann-La Roche, Inc., of Nutley, N.J. (Respondent), submitted exceptions to the findings of fact and conclusions of law and the tentative order, and oral argument on these exceptions was heard on November 5, 1969, before the Director of the Bureau of Narcotics and Dangerous Drugs. At that time, the Director decided that the record should be updated in the areas of diversion and illegal use of these drugs.

Accordingly, an order was published in the FEDERAL REGISTER of April 8, 1970 (35 F.R. 5695), calling for a supplemental hearing. Under the terms of the order establishing the supplemental hearing and in accordance with a joint recommendation of counsel, the scope of the supplemental hearing was limited to evidence bearing on the use of Librium or Valium in conjunction with, or related to, the abuse of other drugs, including rebuttal evidence from Respondent bearing on whether such abuse occurred, its nature, frequency, relevancy, and significance. Mr. Edgar A. Buttle was appointed as hearing examiner by the U.S. Civil Service Commission.

As indicated in the joint recommendation, the presentation by the Government of other evidence of abuse, together with Respondent's rebuttal evidence, would have inordinately protracted the hearings. Additionally, for the most part, such evidence would have been cumulative; that is, showing a continuation of circumstances existing at the time of the prior hearing in 1966. As a consequence, evidence relating to international overdoses and attempted suicides; evidence concerning suicides and other deaths in which the drugs played a significant role; reports of audits of retail drugstores detailing significant shortages which could not be legitimately accounted for; and police reports showing instances in which the drugs were discovered by police during their investigation of drug and other criminal offenses suggesting use and distribution outside of the legitimate channels, were neither to be presented nor rebutted by either side inasmuch as essentially the same type of evidence had already been adduced at the prior hearing.

Proposed supplemental findings, based upon the evidence adduced at the supplemental hearing, were published in the FEDERAL REGISTER of November 24, 1970 (35 F.R. 17998) with any interested person permitted 30 days from the date of publication to file written exceptions. By a letter dated December 2, 1970, Respondent requested an extension of time for filing exceptions until January 21, 1971. On December 4, 1970, the Director, by letter, granted an extension to January 6, 1971, upon which date Respondent filed its exceptions accompanied by a brief, which included a request for oral argument on its exceptions before the Director. By letter of January 13, 1971, the request was denied on the grounds that the lengthy supplemental hearing, the size of the record developed and its written exceptions and brief presented Respondent's position with such comprehensiveness that oral argument would result in unjustified delay not in the public interest.

Upon due consideration of the exceptions to the proposed supplemental findings of fact, published November 24, 1970, the supplemental findings of fact, as amended to reflect any meritorious exceptions, are hereby incorporated with the proposed findings of fact and conclusions and tentative order, published May 21, 1969, also amended to reflect meritorious exceptions, to comprise the following final findings of fact and conclusions and final order.

FINDINGS OF FACT

THE NATURE, EFFECTS, AND USES OF LIBRIUM AND VALIUM

1. The benzodiazepines, of which chlordiazepoxide (Librium) was the first synthesized, are a new class of drugs, different chemically from the barbiturates or any other drugs known at the time of their syntheses (Zbinden, Tr. 2080–84; R–142C; R–119; Lofft, Tr. 531).

2. Chlordiazepoxide (Librium) is a benzodiazepine compound with the following chemical formula:

7 - chloro-2-methylamino-5-phenyl-3H-1-, 4-benzodiazepine, 4-oxide hydrochloride.

It is a colorless crystalline substance; is soluble in water and its molecular weight is 336.22 (R–119).

3. Diazepam (Valium) is a benzodiazepine derivative with the following chemical formula:

7-chloro-1, 3-dihydro-1-methyl-5-phenyl-2H-1, 4-benzodiazepine-2-one.

It is a colorless crystalline compound insoluble in water and its molecular weight is 284.74 (R–120).

4. Experimental studies of their effects in animals were conducted by the Respondent. These tests indicated that Librium and Valium are depressant drugs having a marked calming action on the central nervous system at lower doses. An increase in dose resulted in more pronounced effects on the central nervous system, i.e., drowsiness, motor incoordination or ataxia, and sleep. On the basis of specially designed experiments whereby excitation was induced by surgical or chemical means, or by putting the animals under stressful conditioned behavior situations, the benzodiazepines produced an antiexcitatory effect at dose levels below those that cause nerotoxicity or oversedation, thus suggesting a usefulness in the treatment of anxiety and tension. The benzodiazepines are not generally recognized as effective sedative-hypnotic agents within the normal dosage range (Zbinden, Tr. 2199–2204; R–142; Lang (1963), R–145; Heise (1961), R–146).

5. The Respondent also presented evidence concerning the results of experimental tests on animals, designed to determine the primary site of action of the benzodiazepines. Primary site of action is defined to mean the location in the brain where a drug at the lowest dose will produce an effect. It is believed that the primary site of action of these drugs is in the subcortical structures of the brain. The precise site of action cannot be determined with certitude. Dr. Gerhard Zbinden of Roche Laboratories stated that their tests showed it to be in the hippocampus (Tr. 2187–88). However, Dr. Harold Himwich, another Respondent witness, testified that his tests showed that the area most sensitive to low doses of Librium and Valium, was in the transmission from the amygdala to the hippocampus (Tr. 2677). Moreover a doubling of the dose in these tests done at Roche Laboratories resulted in the drug effect spreading to the cortex, the area of the brain associated with judgmental functions. (Zbinden, Tr. 2187; R–142S.) When the dose was further increased the whole brain was involved (Tr. 2188).

6. Librium and Valium are widely used in the treatment of anxiety and tension, as muscle relaxants, as anticonvulsants, and as antidepressants.

7. Librium has been in general medical use since 1960. More than 6 billion capsules of the drug have been commercially distributed, and millions of patients have taken Librium since its approval by the Food and Drug Administration (Bennett, Tr. 4135–36; R–222).

8. Librium is indicated whenever fear, anxiety and tension are significant components of the clincial profile.

In low oral doses, the drug is effective in mild to moderate anxiety and tension, tension headache, preoperative and postoperative apprehension, premenstrual tension and menstrual stress, chronic alcoholism, behavior disorders in children, and whenever anxiety and tension are concomitants of gastrointestinal, cardiovascular, gynecologic or dermatologic disorders.

Skeletal muscle spasticity (resulting from spinal cord injury, congenital or acquired brain damage) and other debilitating neuromuscular disorders such as dystonia and athetosis frequently respond to Librium. Painful muscle spasm

associated with myositis, fibrositis, bursitis, tenosynovitis, arthritis, fractures, intervertebral disc syndrome, whiplash injury, low back pain or postural strains is often benefited when emotional factors are present.

In higher oral doses, Librium is of value in the more severe anxiety and tension states, agitated depression and ambulatory psychoneuroses (e.g., acute and chronic anxiety states, phobias, obsessive-compulsive reactions and schizoid behavior disorders). In addition, it may be useful in certain types of acute agitation due to chroinc alcoholism or alcoholic withdrawal (including delirium tremens), hysterical or panic states, paranoid states and acute stages of schizophrenia (R–119).

9. Diazepam (Valium) is of use in dealing with anxiety reactions stemming from stressful circumstances or whenever somatic complaints are concomitants of emotional fators. It is useful in psychoneurotic states manifested by anxiety, tension, fear, and fatigue.

Valium may also be useful in acute agitation due to alcohol withdrawal.

Valium may be of use to alleviate muscle spasm associated with cerebral palsy and athetosis (R–119).

10. Librium and Valium have also been used in the treatment of epilepsy (Gibbs, Tr. 2241–42). Dr. Fredrick E. Gibbs, a renowned expert in the field of electroencephalography, testified that he found Valium most effective in the treatment of petit mal variance, a condition usually associated with very severe convulsions with neurological signs and symptoms (Gibbs, Tr. 2252). Valium has also been used in the management of status epilepticus (Gibbs, Tr. 2142–45).

11. Librium is considered by many physicians to be the drug of choice in the treatment of acute alcoholism (Chambers, Tr. 1625; Kissen (1961), R–91; Armour (1963), R–51). Librium given intramuscularly at sufficient doses suppresses and prevents a number of the symptoms of alcohol withdrawal, i.e., tremor, hallucinations, delerium tremens, and convulsive seizures. (Lofft, Tr. 532, 558; Chambers, Tr. 1625; D'Agostino, Tr. 3812–15; Armour (1963), R–51, p. 369–70; Hoff (1963), R–85, p. 152; Kissen (1961), R–91, p. 106; Morrison (1963), R–99, p. 431; Lawrence (1960), R–93). Librium does not prevent al symptoms of alcohol withdrawal but rather "makes the withdrawal from alcohol less painful" (Kendis, Tr. 2874); "makes [hallucinations] less terrifying" (Kendis, Tr. 2885; also Short and Moore (1965), R–227, p. 1204); and "calms the patient markedly, [and] diminishes anxiety and restlessness" (Rosenfield & Brizzoco (1964), R–228, p. 83).

PSYCHIC AND PHYSICAL DEPENDENCE, TOLERANCE, WITHDRAWAL SYMPTOMS, AND OTHER HAZARDS TO HEALTH AS FACTORS IN DETERMINING POTENTIALITY FOR ABUSE

12. The existence of psychic dependence is one of the elements in assessing abuse liability. Psychic dependence on a drug (habituation) has developed when "the effects produced by a drug, or the conditions associated with its use, are necessary to maintain an optimal state of well-being" (Jaffe (1965), R–133, p. 285). It involves "a belief on the part of the subject that he must experience the effect of a drug" (Deneau, Tr. 1028). It is "a situation in which getting the drug, taking the drug, safeguarding his supply, becomes one of his major motivations in life" (Isbell, Tr. 1546).

13. The World Health Organization Expert Committee on Addiction Producing Drugs has described the problem of psychic dependence in these terms: "[Individuals] may become dependent upon a wide variety of chemical substances that produce central nervous system effects ranging from stimulation to depression. All of these drugs have one effect in common: They are capable of creating, in certain individuals, a particular state of mind that is termed 'psychic dependence'. In this situation, there is a feeling of satisfaction and a psychic drive that require periodic or continuous administration of the drug to produce pleasure or to avod discomfort. Indeed, this mental state is the most powerful of all the factors involved in chronic intoxication with psychotropic drugs, and with certain types of drugs it may be the only factor involved, even in the case of most intense craving and perpetuation of compulsive abuse" (Eddy, et al. (1965), G–81, p. 723; Tr. 1104–05).

14. The habitual use of a substance, per se, does not necessarily imply psychic dependence. Chronic diseases such as diabetes require continual drug treatment, and this does not imply psychic dependence. (Seevers (1962), R–131, p. 94; Deneau, Tr. 1035.) In sum, psychic dependence is "something more than simply symptomatic relief" (Eddy, Tr. 1105–06).

15. Substantial evidence of record establishes that individuals have developed psychic dependence to Librium and Valium. The uncontested testimony of physicians was that patients find the two drugs pleasant to take (Murray, Tr. 364; Barten, Tr. 454; Evans, Tr. 813–15, 829–30). They provide an inner sensorial feeling that is gratifying to the patient (Uzee, Tr. 907). Patients were reported to have been apprehensive about being without their supply of the medication and expressed to their physicians a reluctance to come off the drugs. Individuals have attempted unsuccessfully to discontinue taking Librium and Valium when a dependency has developed. Still other patients have gone to excessive lengths to maintain their supply of the two drugs. (Lofft, Tr. 1560; Evans, Tr. 817, 825; Uzee, Tr. 905–06; Galen, Tr. 1443–48; Chelton, Tr. 1672; Williams, Tr. 1757–59; Gulle (1963), G–14; Lingjerde (1965), G–55; Wenkstetten (1965), G–91, Table 3; Kranz (1965), G–94 pp. 8–9.) This experience confirms the opinion expressed by experts that Librium and Valium are drugs to which individuals can and do develop psychic dependence. (Eddy, Tr. 1077; Isabell, Tr. 1552–54; Eddy, et al. (1965), G–81, 727.)

16. Respondent has adduced evidence by the testimony of practicing physicians and reports from the medical literature that psychic dependence to Librium and Valium has not been encountered in extensive clinical use over many years (Cohen, Tr. 324; Feldman, Tr. 3683; D'Agostino, Tr. 3819; Stanfield, Tr. 3814; Schicle, Tr. 4933; Harris & Cohen (1960), R–81; Farb (1961), R–78; Cohen and Harris (1961), R–63; Moore (1962), R–98; Reiser (1962), R–86; Bragan (1963), R–58; Levy (1963), R–95; Burnett & Holman (1965, R–61). This does not rebut the evidence introduced by the Government. The doctors appearing on behalf of the respondent were administering Librium and Valium generally at conservative therapeutic levels, not in excess of recommended doses, and were closely supervising the drug therapy of their patients.

Such evidence tends to confirm the following estimation set forth in the final report of the President's Advisory Commission on Narcotics and Drug Abuse of 1963:

> Drug abuse is not a uniform problem throughout the country, and even in the areas of the highest incidence few medical practitioners come into contact with the afflicted. It is estimated that most medical practitioners never see a habitual drug abuser [G. Ex. 331, p. 57].

17. Drugs which are capable of producing euphoria are particularly susceptible to being abused. Euphoria is defined as "an exaggerated sense of well being." (21 CFR 166.2(c)(2).) The evidence establishes that euphoria has been reported following use of Librium and Valium. (Barten, Tr. 454; Chambers, Tr. 1628; Domino, Tr. 4617; Zbinden et al. (1961), R–118, pp. 627, 634; Gulle (1963), G–14, p. 57; Towler et al. (1962), R–73, p. 833; Darling (1963), G–48, p. 502.)

18. The Respondent introduced the results of two experimental studies designed to explore the capacity of Librium and Valium to produce psychic dependence. The experimental procedures used in these studies are in the early stages of their development and, although promising, have produced inconclusive results.

The study reported by Gerald A. Deneau involved the self-administration of Librium to five Rhesus monkeys. He has developed equipment which permits the animal to self-administer the drug but which still restrains the animal sufficiently for the purpose of the experiment. The number of injections of a drug which an animal self-administers is electronically recorded on a strip chart, from which it is possible to compute the total doses taken by the animal during a given period of time. Of the five monkeys tested, one took essentially no drugs at all. The other four self-administered Librium to some extent on an erratic basis (Deneau, Tr. 2300). Two of the four monkeys failed to take pentobarbital—a drug with a proven abuse liability and which was used as a control in the test—in any consistent way (Tr. 2306, 2308). The remaining two monkeys showed an erratic pattern of self-administration,

sometimes taking no Librium or pentobarbital for a period of several days and then spontaneously self-administering as much as they could physically withstand (Tr. 2309–10). The experiments, which were complicated by several technical failures (Tr. 2305–07), were very difficult to interpret by Dr. Deneau (Tr. 2311).

The study reported by Alberto Di Mascio, Ph. D., involved the observation of behavior effects in humans following administration of various central nervous system drugs, including d-amphetamine, secobarbital, meprobamate, Librium, and Valium. The essential method of these studies is to administer a battery of standard tests to a group of subjects, then to administer the drug being tested to one group and placebo to another, and then to repeat the same tests, in order to compare the changes in the scores following administration of the drug, with the changes occurring after administration of the placebo. (Di Mascio et al. (1963), R–167.) The test subjects were given mild, tranquilizing doses of Librium (5 mg. t.i.d./10 mg. t.i.d.) and Valium (2 mg. t.i.d./5 mg. t.i.d.). They received high, sleep-promoting doses of secobarbital (100 mg./200 mg.) (R–170 (F) (1) and (2)). At these low dosages, Dr. Di Mascio's subjects did not report that they had experienced a euphoric-like effect (Di Mascio, Tr. 4458).

19. "Tolerance" is an adaptive process which contributes to abuse because, where it exists, a person tends continually to increase the amount of drug being taken. Tolerance has developed when, after repeated administration, a given dose of a drug produces a decreasing effect or conversely when increasingly larger doses must be administered to obtain the effects observed with the original dose (Jaffe (1965), R–113, p. 285; Deneau, Tr. 1009).

20. Tolerance occurs with a great many drugs which, on the basis of clinical experience, have been found to be both addicting and nonaddicting in character, and therefore, "the phenomenon of tolerance by itself is not a reliable index of abuse liability" (Deneau, Tr. 1010). However, "Tolerance enables the central nervous system to bear exposure to larger and larger concentrations of the drug, and it permits the optimal development of those adaptive processes, probably of a biochemical nature, which lead to physical dependence." (Seevers (1962), R–131, p. 95).

21. There was evidence of reports from the medical literature that drowsiness and ataxia in patients on given doses of Librium and Valium have disappeared within a few days with no reduction in dose (Grayson (1962), G–66, p. 10; Youngblood (1964), G–75, p. 2107; Scherbel (1961), G–29, p. 280; Domino, Tr. 4698–4701).

22. There was also evidence that patients have increased their dosage in order to maintain relief of anxiety (Uzee, Tr. 913, 919; Mr. E., Tr. 494–95; Lingjerde (1965), G–55, p. 3). To date, however, there have been few such reports in the medical literature and Respondent's witnesses have testified that tolerance to Librium and Valium has not been encountered in extensive use over many years (Gibbs, Tr. 2263–64; D. Feldman, Tr. 2532–33; Bercel, Tr. 2653–54, 2657; Scherbel, Tr. 2821; Goldman, Tr. 2914; Friend, Tr. 2937; Cohen, Tr. 3218, 3220; Schwab, Tr. 3383–84; D. Feldman, Tr. 3682; Knott, Tr. 3716; D'Agostino, Tr. 3817; Stanfield, Tr. 3844; Snell, Tr. 3884; Smith, Tr. 3924; Schiele, Tr. 4033; Greenberg, Tr. 4060). The evidence establishes that it is possible to develop tolerance to Librium and Valium but that it has not been frequently observed or reported.

23. The evidence shows that Librium has been used widely and with satisfactory results in the treatment and rehabilitation of alcoholic patients (Kendis, Tr. 2867; Rosenfeld, Tr. 3422; Hoff (1963), R–85, p. 152). There is some evidence that Valium has also been used with alcoholic patients without encountering abuse (Hoff (1963), R–85, pp. 150, 152; Burdine (1964), R–59, p. 591).

24. Although expert medical witnesses testified that they had not observed Librium or Valium to produce any sensorial effect that could be characterized as a "kick" or "high," there was substantial evidence adduced by the Government to the effect that patients with alcoholic problems had abused the two drugs either alone or in combination with alcohol to the point of intoxication. (Lofft, Tr. 536, 555, 557; Uzee, Tr. 907–08; Chambers, Tr. 1629; Chelton, Tr. 1669–70, 1673; Williams, Tr. 1741, 1747, 1749; Kjolstad (1964), R–92, p. 7.)

25. Physical dependence is a major factor in causing drug abuse. The World Health Organization Expert Committee on Addiction-Producing Drugs has defined physical dependence as "an adaptive state that manifests itself by intense physical disturbances when the administration of the drug is suspended * * *. These disturbances, i.e., the withdrawal or abstinence syndrome, are made up of specific arrays of symptoms and signs of psychic and physical nature that are characteristic for each drug type. These conditions are relieved by readministration of the same drug or of another drug of similar pharmacological action within the same generic type." (Eddy et al. (1965), G–81, p. 723). The production of a withdrawal syndrome or a withdrawal illness upon discontinuation of the drug "is the only way one can demonstrate that physical dependence exists." (Deneau, Tr. 1011–12).

26. Discussing physical dependence, Dr. Martin Seevers states "Among depressant drugs, the order of magnitude of abuse is: (1) Alcohol, (2) the morphine-like analgesics, and (3) the barbiturate-like sedatives. With these drugs, abuse is enhanced by the development of physical dependence, and the compulsion to continue taking the drug is reinforced by fear of the mental and physical agonies of withdrawal. However, although physical dependence is only rarely a primary factor leading to compulsive abuse, in those drugs that induce it, it is a potent factor favoring continuance of abusive use." (R–131, p. 95.)

27. Nonnarcotic drugs, such as the barbiturates, which produce demonstrable physical dependence usually do so only on extremely high doses continued over a long period of time. To produce physical dependence maximally, one must administer the drug frequently enough so that the subject is under continuous drug effect, and in doses such that the effect is rather pronounced, and for prolonged periods of time. (Deneau, Tr. 1014.)

28. The demonstration of physical dependence, either experimentally or spontaneously, does not mean that the drug involved will necessarily produce psychic dependence. (Eddy, et al. (1965), G–81, p. 723.) Morphine, for example, has been administered to patients in hospitals thousands of times even over prolonged periods of time without the development of psychic dependence. This occurs because the patient accepts the drug for symptomatic relief and does not become personally involved in its administration (Eddy, Tr. 1106–07.) However, it is now generally accepted that physical dependence to a drug is a strong reinforcing factor for the development of psychic dependence (Isbell, Tr. 1555, 1565, 1569–71, 1581).

29. Dr. Leo E. Hollister directed the only controlled study to determine whether it is possible to produce withdrawal reaction from Librium. In this study large doses of Librium, several times the customary therapeutic dosage levels, were administered to 38 patients, most of whom were schizophrenics, over a 6-month period. In 11 of these patients, treatment with the drug was abruptly terminated by substituting a placebo, in a conscious attempt to determine whether they would experience withdrawal symptoms. The dosage used in these 11 patients ranged from 300 to 600 mgs. daily; six patients received the latter dose. Duration of treatment varied from 2 to 6 months, 10 patients having been treated for 5 months or longer (G–16A, p. 64).

30. Dr. Hollister has summarized his observations as follows: "When they were withdrawn we found that 10 out of 11 patients experienced new symptoms or signs which could have been due to drug withdrawal. I emphasize 'could have been' because many of the symptoms of drug withdrawal are similar to those one ordinarily treats with these drugs, and there is also a problem in determining which is which." (Tr. 301–02.) "Although differentiating withdrawal reactions from recrudescent psychiatric symptoms after drug withdrawal is always difficult, a number of factors favored the former interpretation of the newly appearing symptoms and signs. First, the frequency (10 of 11 patients) of new symptoms or signs soon after withdrawal. Second, their coincidence with decreasing plasma levels of drug Third, postwithdrawal seizures in two patients. Fourth, a slower onset and subtler development of this syndrome

than that from meprobamate or barbiturates. This difference is consonant with the slower decline in plasma levels of chlordiazepoxide, whose half-life is 48 hours as compared with 24 hours for meprobamate (Hollister and Glazener, 1960b)." (Hollister (1961), G–16A, p. 67.)

31. Dr. Hollister stated that the withdrawal reactions "in general * * * would resemble withdrawal to alcohol, barbiturates or meprobamate, with the major distinguishing feature being the timing. The withdrawal syndrome here was attenuated and delayed. Instead of getting all symptoms early, as you usually get with the other drugs, within 24 to 48 hours, you did not begin to develop symptoms until after 48 hours. Then they appeared somewhat subtly and insidiously." (Tr. 307).

32. Dr. J. L. Bennett conducted a study in which Valium was administered to groups of schizophrenic patients for a period of 6 weeks (Hollister, Bennett, et al. (1963), G–69). The purpose of the study was "to test the effect after the completion of 6 weeks * * * of abrupt withdrawal of the drug from the patient, by the substitution of an inert placebo medication so that the patient was not aware the drug was being withdrawn." (Bennett, Tr. 229). These patients were given 30 mg. of Valium per day for the first week, with the dosage being progressively increased to 60 mg. per day, 80 mg. per day, and finally reaching 120 mg. per day in the fourth week of the study. In 13 patients the drug was abruptly stopped. Dr. Bennett described symptoms in six of the 13 patients which he attributed to the abrupt withdrawal of the drug, including one who had preconvulsive symptoms of tenseness, rigidity, and loss of consciousness and another who had a grand mal seizure on the 8th day after withdrawal. Defining physical dependence as a state in which such physical symptomatology is manifested upon withdrawal, he concluded that such physical dependence could develop with Valium "at the dosage that was used" (Tr. 234).

33. Librium and Valium have been taken in excessive amounts for extended periods of time by individuals to the point that they have become physically dependent on the drug. When use of the drugs has been abruptly discontinued, some of these persons have experienced symptoms associated with the barbiturate abstinence syndrome (see Lofft, Tr. 534–35, 541; Eddy, Tr. 1096–97; Isbell, Tr. 1547–48; G–81, pp. 725–26; R–133, p. 297). These symptoms as evidenced include:

(a) Increased tension and anxiety (Mr. E., Tr. 501–02; Lofft, Tr. 546; Uzee, Tr. 919; Williams, Tr. 1747, 1749, 1750–51);

(b) Insomnia (Lofft, Tr. 544, 548–49; Williams, Tr. 1749);

(c) Restlessness (Barten, Tr. 448; Lofft, Tr. 543; Chelton, Tr. 1673; Williams, Tr. 1747, 1748, 1754);

(d) Tremulousness (Lofft, Tr. 543; Uzee, Tr. 908–09, 921);

(e) Muscle spasms (Mr. E., Tr. 502; Lofft, Tr. 544, 546);

(f) Hallucinations (Barten, Tr. 447–48; Lofft, Tr. 540–41; Uzee, Tr. 915; Williams, Tr. 1744);

(g) Grand mal seizures (Bennett, Tr. 241; Hollister, Tr. 305; Barten, Tr. 448; Lofft, Tr. 540, 611; Williams, Tr. 1751–52); and

(h) Confusion and disorientation (Barten, Tr. 447–48; Lofft, Tr. 540–43; Uzee, Tr. 907–08, 921).

34. Dr. John G. Lofft, a psychiatrist and specialist in the treatment of alcoholism and allied addictions, testified that the abstinence syndrome associated with Librium and Valium withdrawal compares to that experienced after abrupt withdrawal from barbiturates (Tr. 550). It is characterized in its mildest form by insomnia and increased anxiety (Tr. 548–49). When the patient has been taking elevated doses for long periods of time the withdrawal syndrome is marked by restlessness, tremulousness, muscle pains, perspiration, hallucinations, and sometimes, although not frequently, convulsive seizures (Tr. 540, 543, 547). The severity of the withdrawal is dependent upon the degree of dependence, and the amount of drug the person has been taking (Tr. 551–52; Jaffe (1965), R–133, p. 289). Librium-Valium withdrawal differs from the barbiturate withdrawal syndrome in that it persists over a longer period of time (Lofft, Tr. 550–51).

35. The evidence also indicates that those individuals who showed signs of Librium or Valium dependence usually had experienced difficulty with similar drugs before—most often alcohol (Lofft, Tr. 553; Evans, Tr. 820; Uzee, Tr. 905; Chambers, Tr. 1626–29; Chelton, Tr. 1670, 1674). These "dependent personalities", as they have been characterized, look for chemical solutions to a variety of problems. They will reduce a dependency on alcohol by moving to a different but related dependency (Lofft, Tr. 552–53). Sometimes the pattern of dependency is multiple in nature, e.g., Librium and alcohol together, Librium and a barbiturate, etc. (Lofft, Tr. 536; Evans, Tr. 819–20; Uzee, Tr. 907; Isbell, Tr. 1558; Chambers, Tr. 1632; Chelton, Tr. 1671; Williams, Tr. 1741).

36. Substantial evidence of record demonstrates that Librium and Valium taken in excessive doses produce intoxication which is manifested by staggering gait, drowsiness, slurred speech, and poor coordination (Bennett, Tr. 241–42; Barten, Tr. 447; Lofft, Tr. 539–40, 555; Evans, Tr. 812, 823–24; Galen, Tr. 1434–37; Chelton, Tr. 1669–70, 1673–75; Lemere (1960), G–20; J. Miller (1962), G–22; Murray (1960), G–23; Barten (1965), G–42).

37. There was further evidence that Librium at moderate doses has some effect upon judgment and that at elevated doses it may reasonably be expected to impair a person's ability to operate an automobile with normal alertness required to insure safety (Bennett, Tr. 242; Murray, Tr. 329–45; Lofft, Tr. 554; Eddy, Tr. 1097; Chelton, Tr. 1675; J. Miller, Tr. 3349–54, 3374–75; J. Miller (1962), G–22; Murray (1960), G–23).

38. There was some evidence indicating that Librium may produce a paradoxical rage reaction, i.e., an excitable and exhilarated state whereby the individual may become a danger to himself and to others. This reaction has been manifested in isolated instances by a hostile and irritable mood to a point where the person taking Librium has become violent and has physically threatened the lives of others (Murray, Tr. 355–56, 357–59, 360–63; Barten, Tr. 447; Lofft, Tr. 558; Gibbs, Tr. 2254–55; Stanfield, Tr. 3860–61; Murray (1962), G–24; Bowes (1965), G–44, p. 338; Krakowski (1963), G–51, p. 49; Dean (1962), R–70, p. 4).

39. Some physicians have prescribed Librium and Valium extensively for a wide variety of patients and have never encountered any difficulty in discontinuing the drugs or observed any withdrawal reaction. (Gibbs, Tr. 2258; D. Feldman, Tr. 2531; Rothman, Tr. 2586, 2622; Bercel, Tr. 2661–63; Scherbel, Tr. 2803; Goldman, Tr. 2912; Friend, Tr. 2936; Cohen, Tr. 3217, 3219–20, 3228; Meverson, Tr. 3653–54; P. Feldman, Tr. 3683, 3690; Knott, Tr. 3717; Stanfield, Tr. 3849; Snell, Tr. 3888; Smith, Tr. 3925; Schiele, Tr. 4033; Greenberg, Tr. 4060; Bitman (1966), G–62). But this is not surprising since overt evidence of physical dependence to any of the sedative drugs is not seen unless the individual has maintained a concentration in his organism well above the therapeutic level (Eddy, Tr. 112–13). Also see Finding No. 16.

DIVERSION FROM LEGITIMATE DRUG CHANNELS

40. The evidence indicates that some pharmacists are distributing amounts of Librium without authorization from physicians. During a 5-year period extending from 1961 through 1965, U.S. Food and Drug Administration records show that there were 35 completed prosecutions involving the drug chlordiazepoxide, all of which were terminated in convictions. These 35 cases involved 132 illegal buys of the drug, made either without a prescription or as requests for a refill when no refill was authorized. Investigation in three of these cases was initiated following complaints that a druggist had illegally dispensed Librium. (Clevenger, Tr. 1846.) At the close of the investigations in 14 of these cases, Food and Drug Inspectors checked the records, invoices, and prescription files of the drugstores involved. On the basis of investigation it was estimated that in each case between 47 percent and 100 percent of the pharmacies' supply of chlordiazepoxide had been dispensed without authorization of a physician. An average of 75 percent of the total amount of the drug dispensed by the pharmacists involved in these instances could not be accounted for. This amounted to over 54,000 capsules (Clevenger, Tr. 1799–1807, 1815, 1834–36; G–268). See also Ashcraft, Tr. 1158, 1519; Witness X, Tr. 1895–97 for other evidence to the same effect.

41. In the foregoing connection, Agent "X", a regular employee of the Bureau of Drug Abuse Control, testified to illegal purchases made by him of five 25 mg. capsules of Librium from one "S.H." on August 19, 1966 (Tr. 1891) and another of thirty 25 mg. Librium capsules on August 23, 1966 (Tr. 1896) from a pharmacist.

42. Another FDA employee, Agent "Y", stated that he purchased one hundred 10 mg. capsules of Librium from a heroin addict on August 30, 1966, 2 days before he testified in this case (Tr. 1907).

43. Also, Mr. "B", a "part-time employee of the Food and Drug Administration and part-time hotel clerk, in Kansas City" (Tr. 1210), testified concerning six sales of Librium observed by him at various bars and on the street in Kansas City, Mo. These cases are pending and there have been no convictions. (Tr. 1217–1232; Ashcraft, Tr. 1166–69.)

44. Respondent, on the other hand, adduced evidence on the subject of illicit traffic through witnesses; Alfred J. Murphy, Senior Inspector, Drug Control Section, Division of Food and Drugs, Massachusetts Department of Mental Health (Tr. 3749); Lt. James Hitchcock, Commanding Officer, Intelligence Unit, Kansas City Police Department (Tr. 3625); John E. Storer, Chief, California Bureau of Narcotic Enforcement (Tr. 3601); Willis A. Roose, Chief, Drug Section, Food and Drug Division of the Indiana State Board of Health (Tr. 3528) and Robert Merritt, Supervisor, Division of Investigation, California Department of Professional and Vocational Standards (Tr. 3463). These investigators testified that they had not encountered a significant illicit traffic in Librium in their communities. However, some diversion of the drug had been encountered. (Murphy, Tr. 3760–67; Hitchcock, Tr. 3637–38, 3643; Roose, Tr. 3539–40.)

45. There is evidence that individuals have obtained chlordiazepoxide in excess of the amounts prescribed and without authorization of a physician by:

(a) Returning for a renewal of a prescription before the supply of the drug would normally have run out (Mr. E., Tr. 496; Perras, Tr. 690–91; Lash, Tr. 723–24);

(b) Obtaining concurrent prescriptions for the drug from several physicians (Perras, Tr. 691; Lash, Tr. 722–23; Sagansky, Tr. 987–89; Galen, Tr. 1433, 1440; Williams, Tr. 1749, 1759);

(c) Receiving it from relatives and friends (Williams, Tr. 1748, 1750, 1759; Rothman, Tr. 2607; G–101, G–193);

(d) Illegal purchases of the drug (Cohen, Tr. 833–96; Mr. B., Tr. 1219, 1223, 1227–28; Fenton, Tr. 1395; Chambers, Tr. 1630); and

(e) Stealing the drug (G–112; G–113; G–178).

46. Patients have increased the prescribed dosage of Librium on their own initiative for the relief of anxiety (Murray, Tr. 360; Mr. E., Tr. 494–95; Uzee, Tr. 908; Galen, Tr. 1434–38; Chelton, Tr. 1670, 1671, 1673; Williams, Tr. 1748, 1749, 1751; Guile (1963), G–14; Lingjerde (1965), G–55; G–112; G–113).

INDIVIDUALS TAKING DRUG ON THEIR OWN INITIATIVE RATHER THAN ON THE BASIS OF MEDICAL ADVICE

47. The evidence herein indicates that Librium and Valium have been taken in large amounts in what appeared to be suicide attempts (Spellman, Tr. 649–51; Lash, Tr. 714–15, 719; Galen, Tr. 1440–42; Verhulst, Tr. 1488–1505; Chambers, Tr. 1633–36; Bercel, Tr. 2666; Stanfield, Tr. 3857–60; Clarke, et al. (1961), G–6; Ehlers (1963), G–9; Gilbert (1961), G–13; Smith (1961), G–32; Bowers (1965), G–44; Kranz (1965), G–94, p. 11; G–99; G–225(B); G–226(B); G–227(B); G–261; G–262; G–282; G–288; G–289; G–290; Stanfield (1961), R–111; Zbinden (1961), R–118; Boxall (1966), 198).

48. Studies of suicide and attempted suicide, and their general patterns, have been reported in the medical literature and were introduced into evidence (Hirsch, Zauder and Drolette, "Suicide Attempts with Ingestants", Archives of Environmental Health, Vol. 3, July–December 1961, p. 212 (G–93); Grahan, J. D. P., "The Diagnosis and the Treatment of Acute Poisoning" (extracts), Oxford Medical Publications, 1962 (R–219); ibid. (Ch. 19), "Attempted Suicide by Poisoning" (R–219A)). These studies were supplemented in the evidence in this proceeding by the testimony of Dr. James A. Knight, Professor of Psychiatry and Assistant Dean of the Tulane University School of Medicine (Tr. 4351). Rather definite patterns exist across the spectrum of population, and what may be expected can be predetermined within these patterns regardless of the agent employed. There are demonstrable differences in age, sex, and occupation groups. The pattern of unsuccessful attempts is different from that where the attempt was successful (R–226). The distribution of the cases of attempted suicide with Librium and Valium both by age and sex, conforms to the distribution shown in these studies, and that generally encountered in medical practice (Knight, Tr. 4346–47).

49. The testimony produced at the hearing dealing with cases in which Librium or Valium have been taken in a suicidal attempt or gesture, including that of the Government's witnesses, shows that these drugs appear sometimes as an agent used in suicidal attempts for the very reason of their known safety for the use with a patient population in which there is a high incidence of such attempts (Lash, Tr. 739; Knight, Tr. 4354; Snell, Tr. 3887).

50. The Government has not contended that either Librium or Valium caused a patient to attempt suicide.

51. Numerous reports from the medical literature indicate that individuals have recovered following large overdoses of Librium and Valium (Clark (1961), G–6; Gilbert (1961), G–13, p. 309; Schaefer (1962), G–28, p. 164; Smith (1961), G–32; Ehlers (1963), G–9). However, this does not minimize the evidence that intentional overdosages of either Librium or Valium taken alone or together with other sedative drugs (including alcohol), have depressed the central nervous system to the point of causing stupor, semicoma, coma, and in some instances, death. (Spellman, Tr. 649–51; Lash, Tr. 720; Snoddy, Tr. 1132–40; Galen, Tr. 1441; Chambers, Tr. 1633–36; Gilbert (1961), G–13; Schaefer (1962), G–28; G–99 (b) through (k); G–121; G–129; G–136; G–139; G–150; G–154; G–156; G–157; G–158; G–197; G–221 (a) through (i); G–225(B) (40), (48), (49), (54), (61), (63), (71), (74), (78), (81), (87), (88), (91), (97); G–226 (b) (6), (7), (9), (11), (15); G–227(B), (1), (5), (10); G–241; G–259; G–261 (1), (4), (5), (7), (10), (12), (13), (15), (20), (21), (22), (23), (25), (28), (29), (30), (32), (36), (37), (40), (50), (52), (54), (55), (58); 262 (3), (4), (7), (8), (9), (12), (23), (24); G–288; G–289; G–290.)

52. The evidence indicates that individuals who abuse or misuse drugs sometimes use Librium or Valium in what are apparently self-medication efforts to "crash"[1] from amphetamine intoxication (Lonergan Tr. SL–8[2] through SL–12, SL–17; "Mr. X" Tr. SX–8–9, SX–12, SX–21–23; Beckett Tr. S–123, S–125–126, S–129–130; Ungerleider Tr. S–155; D. Smith Tr. S–384–385, S–391–392, S–401; Strong Tr. S–479, S–488–489; Rosenfeld Tr. S–863–864), to alleviate the untoward effects of LSD and other hallucinogens (Lonergan Tr. SL–8, SL–10–14, SL–16–17, SL–24; "Mr. X" Tr. SX–12, SX–21–23, SX–47; Berson Tr. S–34, S–36–37; Atwell Tr. S–61; L. Smith Tr. S–76–79, S–81–82, S–84–85; Beckett Tr. S–124, S–128; Ungerleider Tr. S–155; D. Smith Tr. S–400–401; Rosenfeld Tr. S–857, S–860–861, S–863–864).

53. The evidence also indicates that some individuals within the illicit drug scene, who are not professional medically trained personnel, administer or give Librium to friends and acquaintances to aid them in recovering from the unpleasant effects of drug abuse ("Mr. X" Tr. SX–13, SX–30–32; Berson Tr. S–34, S–36–37; Atwell Tr. S–61–64, S–69).

54. The evidence indicates that sometimes this self-medication and nonprofessional administration of Librium and Valium is done without proper medical supervision and not pursuant to sound medical advice (Berson Tr. S–34; Atwell Tr. S–61–64; L. Smith Tr. S–77; Beckett Tr. S–123, S–127; Ungerleider Tr. S–155; D. Smith Tr. S–391).

55. Within the medical community, self-medication with Librium, Valium,

[1] The term "crash" has the connotation among the members of the drug scene of mitigating either the effects of symptoms of certain hallucinogens or central nervous system stimulants, most notably LSD and the various amphetamine derivatives. (See Tr. S–78–80 for a drug abuser's definition.)

[2] The transcript of the supplemental hearing which began on Apr. 22, 1970 was numbered consecutively from 1 through 879, with two exceptions: Testimony of Government witness Thomas Lonergan, taken on Apr. 28, 1970, was numbered 1 through 59, and the testimony of Government witness "Mr. X," taken on May 7, 1970, was numbered 1 through 48. Accordingly, references to the testimony of witness Lonergan and "Mr. X," will be prefixed by the letters "SL" and "SX", respectively.

and other prescription drugs is generally considered an unsafe and undesirable practice (Ungerleider Tr. S–180; Greenberg Tr. S–228, S–230–231; Miller Tr. S–343–347; Myerson Tr. S–369; D. Smith Tr. S–404; Kiev Tr. S–437; Strong Tr. S–487; Cahn Tr. S–588; Jones Tr. S–756–757; Rosenfeld Tr. S–867).

56. The evidence does not establish that Librium and Valium are preponderantly the drugs of choice for self-medication purposes by drug abusers. The medical experts generally attribute this to the drugs' ineffectiveness for this purpose relative to other drugs or other methods of treatment (Ungerleider Tr. S–149, S–160–161; Hollister Tr. S–264, S–281–283; Miller Tr. S–328–329, S–331; Myerson Tr. S–357–359; Kiev Tr. S–418; Cahn Tr. S–573–575; Jones Tr. S–724, S–726–727), even though some medical experts are of the opinion that in some instances the drugs are effective in the treatment of drug crisis (Ungerleider Ex. R–S2; Hollister Tr. S–264–265; Miller Tr. S–328–329; Myerson S–359–361; D. Smith Tr. S–386–387; Strong Tr. S–477–478; Cahn Tr. S–578–579; Jones Tr. S–757–758), and to the fact that the drugs are not as pleasurable to take as the more popular drugs such as heroin or the barbiturates. (Miller Tr. S–330, S–334–335; Myerson Tr. S–359, S–361; Kiev Tr. S–417, S–428; Strong Tr. S–477; Cahn Tr. S–559–562, S–572–573, S–580; Jones Tr. S–735–736; Rosenfeld Tr. S–863–864.)

57. The evidence also indicates, however, that the patterns of drug abuse in the United States, including the misuse of drugs for self-medication, while generally falling into definable patterns (Ungerleider Tr. S–142, S–145–147, S–151; Greenberg Tr. S–220–221; Hollister, Tr. S–286–287, S–327, S–353; D. Smith Tr. S–381–383; Kiev Tr. S–415–416; Kirkland Tr. S–452–454; Strong Tr. S–475–476; Cahn Tr. S–555; Bellizzi Tr. S–559–600; Roose Tr. S–652–653; Moss Tr. S–673–674; Jones Tr. S–722–723; Dole Tr. S–833) are cyclical and changing (Ungerleider Tr. S–149–151; Greenberg Tr. S–220; Hollister Tr. S–286; D. Smith Tr. S–383; Kiev Tr. S–415–416; Strong Tr. S–476; Jones Tr. S–722–723).

58. The evidence indicates that the sources of Librium and Valium for the purposes of self-medication or nonprofessional administration are from (1) legitimate prescriptions, either prescribed for the individual or for someone else (Lonergan Tr. SL–21; Berson Tr. S–24, S–43; L. Smith Tr. S–82; Beckett Tr. S–123–124, S–130–131; D. Smith Tr. S–388), (2) forged prescriptions (Beckett Tr. S–125; D. Smith, Tr. S–388), or (3) suppliers of illicit drugs (Lonergan Tr. SL–9–11, SL–23–24; "Mr. X" Tr. SX–14, SX–16, SX–29; L. Smith Tr. S–78–82, S–87), and other sources ("Mr. X" Tr. SX–9, SX–14, SX–45; Berson Tr. S–23, S–26; Atwell Tr. S–61, S–63, S–68; Beckett Tr. S–126; D. Smith Tr. S–389, S–397). The evidence further indicates that Librium and Valium are transferred among individuals within the drug-abusing subculture (Lonergan Tr. SL–16, SL–25; "Mr. X" Tr. SX–9, SX–11, SX–14–16, SX–24, SX–45; Berson Tr. S–24, S–26, S–43; Atwell Tr. S–61–63; L. Smith Tr. S–81; Beckett Tr. S–126; D. Smith Tr. S–388, S–397).

EVIDENCE OF SIMILARITY IN ACTION OF VALIUM TO LIBRIUM

59. The evidence is conclusive that Valium, a more recently marketed drug, is similar in its effect on the central nervous system to that of Librium. Valium is a chemical analog of Librium which shows some quantitative but no significant qualitative differences from Librium (Hollister, Tr. 316; Shideman, Tr. 1301; Zbinden, Tr. 2214–15; Scherbel, Tr. 2796–2803; Schwab, Tr. 3381–88; Darling (1963), G–48; R–119; R–120). Those differences that were noted are not qualitative in nature and at best are of clinical significance only (Chambers, Tr. 1652–53; Gibbs, Tr. 2242, 2245; P. Feldman, Tr. 3678–79; Bowes (1965), G–44, p. 336; Darling (1963), G–48, p. 503).

60. The World Health Organization Expert Committee on Addiction-Producing Drugs has classified drug dependence according to drug types, i.e., drug dependence of the morphine type, of the barbiturate-alcohol type, of the cocaine type, etc. (Eddy, et al. (1965), G–81). This classification is based partly on the ability of drugs within the group to substitute one for another (Isbell, Tr. 1549). Substitution in the context refers to the ability of one drug to suppress partially if not completely the withdrawal symptoms of another drug (Isbell, Tr. 1549). This same phenomenon has been referred to as cross-dependence (Jaffe (1965), R–133, p. 289). Relying on this theory, physicians, as a matter of course, treat patients who show physical dependence on a certain drug by substituting in gradually tapered doses a more manageable drug of the same group (Jaffe (1965), R–133, p. 289). In explanation there was expert medical testimony that drugs which depress the central nervous system act upon different neurons in the brain but that certain drugs have their effect within the same neuronal system (Domino, Tr. 4550–55).

61. The substantial evidence of record establishes that Librium and Valium are among those sedative drugs which substitute for the barbiturates and alcohol. Animal studies demonstrated that Librium effectively suppresses the barbiturate withdrawal syndrome. Further, considerable clinical experience in the treatment of acute alcoholism shows that the benzodiazepines, particularly Librium, effectively suppress the symptoms of the abstinence syndrome in alcoholic withdrawal. (Lofft, Tr. 532; Deneau, Tr. 998–1007; Isbell, Tr. 1586–87; Chambers, Tr. 1624–25; Thomas and Freedman (1964), G–295; D'Agostino, Tr. 3812–15; Domino, Tr. 4648–52, 4717–70; Deneau, G–235; Armour (1963), R–51; Burdine (1964), R–59, p. 591; Kissen (1961), R–91; Morrison (1963), R–99; Jaffe (1965), R–133.)

62. There was expert medical testimony to the effect that individuals who abuse barbiturates or alcohol can be expected to turn to Librium and Valium whenever their drugs of choice are not readily available because the benzodiazepines are known to produce similar effects, to sustain physical dependence of the barbiturate-alcohol type and to prevent barbiturate-alcohol withdrawal. Likewise it is reasonable to assume that they will use Librium and Valium to reinforce the effects of barbiturates and alcohol (Isbell, Tr. 1556–58, 1577–79).

63. The legislative history of the amendments reflects the expectation of Congress, in enacting this legislation, that Librium and similar tranquilizing drugs, would be expeditiously brought under the control of the amendments because of their potential for abuse. Testimony taken before the House Committee on Interstate and Foreign Commerce demonstrated the need for bringing Librium under these controls. (House Report No. 130, 89th Congress.) This committee considered the advisability of listing chlordiazepoxide (Librium) among others by name, but decided not to single out this or any other drug. The committee, however, stated that it expected the Secretary of Health, Education, and Welfare to take early action with respect to the consideration of bringing Librium and other drugs within the controls of the amendments. A similar expectation was expressed by the Senate Committee on Labor and Public Welfare. (Senate Report No. 337, 89th Congress.) (G–228, pp. 2–3; G–229, p. 13; G–230, pp. 24, 33, 38, 43–53, 54–56, 91–92, 101–105, 115–121.)

CONCLUSIONS OF LAW

1. The Drug Abuse Control Amendments of 1965 were intended to protect the public health and safety by establishing special controls for depressant and stimulant drugs. This protection was to be accomplished through increased recordkeeping and inspection requirements, through providing for control over intrastate traffic in these drugs because of its effect on interstate traffic, and through making possession of these drugs, other than by the user, illegal outside of the legitimate channels of commerce.

2. Chlordiazepoxide (Librium) and diazepam (Valium) are drugs with a depressant effect on the central nervous system. They may be legitimately dispensed only upon the prescription of a practitioner licensed by law to administer such drugs, and in full comformity with section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353(b).

3. The substantial, probative, and reliable evidence of record establishes that chlordiazepoxide (Librium) due to its depressant effect on the central nervous system has been abused in the past in the following ways:

(a) There has been significant use of chlordiazepoxide (Librium) in amounts sufficient to create a hazard to the health of the individual and to the safety of other individuals and the community.

(b) There has been significant diversion of chlordiazepoxide (Librium) from legitimate channels.

(c) There has been significant use of Librium by individuals on their own initiative rather than on the basis of medical advice from a practitioner licensed

by law to administer such drugs in the course of his professional practice.

4. Due to the past history of abuse of chlordiazepoxide (Librium), because of its established capacity to substitute for other sedative drugs which are known to be abused and which are now subject to increased controls of the amendments, it is reasonable to conclude that the abuse of chlordiazepoxide (Librium) will continue to increase unless this drug is similarly brought under the control of the amendments.

5. The substantial, probative, and reliable evidence of record establishes that diazepam (Valium) due to its depressant effect upon the central nervous system has been abused in the past in the following manner:

(a) There has been significant use of diazepam in amounts sufficient to create a hazard to the health of the individual and to the safety of other individuals and the community.

(b) There has been significant use of diazepam (Valium) by individuals on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

6. Diazepam (Valium), the newer drug, is so related to chlordiazepoxide (Librium), a drug for which there is considerable evidence of continuing abuse as to make it likely that it will have the same potentiality for abuse.

7. Due to past history of abuse of diazepam (Valium), because of its close relation to chlordiazepoxide (Librium), and because of its established capacity to substitute for other sedative drugs which are known to be abused and which are now subject to controls under the provisions of the Drug Abuse Control Amendments of 1965, it is reasonable to conclude that the abuse of diazepam (Valium) will continue to increase.

8. Chlordiazepoxide (Librium) and diazepam (Valium) are drugs which because of their depressant effect on the central nervous system, have a substantial potential for significant abuse within the meaning of the Amendments, 21 U.S.C. 321(v)(3).

9. Chlordiazepoxide (Librium) and diazepam (Valium) are "depressant or stimulant drugs" within the meaning of 21 U.S.C. 321(v), and are therefore subject to the provisions of 21 U.S.C. 360a. Any drug which contains any quantity of chlordiazepoxide or diazepam is a "depressant or stimulant drug" within the meaning of 21 U.S.C. 321(v)(3) and is also subject to the provisions of 21 U.S.C. 360a.

Therefore, it is ordered, That the stay of effectiveness announced May 17, 1966 (31 F.R. 7174), on the listing of chlordiazepoxide and its salts and diazepam in § 166.3(c)(1) [redesignated § 320.3(c)(1)] as a drug subject to control under the Amendments by the order of March 19, 1966 (31 F.R. 4679), be ended.

It is further ordered, That upon the date on which this order takes effect the applicable provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513) shall apply. Chlordiazepoxide and its salts and diazepam shall be designated as drugs subject to control under schedule IV (21 U.S.C. 812(c)) of the Act and the applicable regulations shall be amended accordingly.

This order shall become effective 90 days from the date of publication in the FEDERAL REGISTER.

Dated: January 30, 1971.

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

[FR Doc.71-1664 Filed 2-5-71;8:46 am]

Title 47—TELECOMMUNICATION

Chapter I—Federal Communications Commission

[FCC 71-102]

PART 0—COMMISSION ORGANIZATION

Establishment of a Spectrum Management Task Force

Order. 1. In recent years, the nongovernment radio communication services have grown tremendously, placing heavy demands on the radio spectrum and resulting in frequency congestion, particularly in heavily populated areas. Several years ago, the Commission began a program to alleviate this situation by first increasing the number of communications channels through channel splitting or shared use and, second, by studies to devise methods of more effective spectrum utilization.

2. The results of a major study for the Commission by Stanford Research Institute concerning Land Mobile Spectrum Utilization (supported by conclusions and recommendations of the President's Task Force on Telecommunications Policy and a report by the Joint Technical Advisory Committee on Spectrum Engineering) indicate that more effective utilization of the spectrum can be obtained by introducing systems engineering concepts and by decentralized or regional frequency management, which recognizes that each area has unique economic, social, demographic and other factors which must be considered in making frequency assignments. Under this approach, regional spectrum management centers will have the capability of monitoring actual channel occupancy and, through a computerized system with a comprehensive data base, assigning the most useful frequencies to Commission licensees. The feasibility of the system has been indicated by the aforementioned studies. The Commission must now organize its resources to design, test and implement this new Spectrum Management Program.

3. In view of the transitional and developmental nature of this program, and the need for flexibility and a concerted effort, we have established a Spectrum Management Task Force, located within the Office of Chief Engineer. This Task Force is responsible for developing policies, plans, systems, and procedures for the Spectrum Management Program and for establishing regional spectrum management centers. After the developmental and testing phases of this program have been completed, the functions and activities of the Task Force and the regional centers will be incorporated into the Commission's permanent organizational structure for continued operation and implementation of such additional regional centers as may be desirable.

4. The amendments set forth below relate to internal Commission organization and practice so that the prior notice provisions of section 4 of the Administrative Procedure Act, 5 U.S.C. 553, do not apply, and the amendments can be made effective immediately. Authority for the promulgation of those amendments is contained in sections 4(i), 5(b), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 155(b), and 303(r).

Accordingly, it is ordered, Effective February 10, 1971, that the rules and regulations of the Commission are amended as set forth below.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; 47 U.S.C. 154, 155, 303)

Adopted: February 1, 1971.

Released: February 2, 1971.

FEDERAL COMMUNICATIONS COMMISSION,[1]

[SEAL] BEN F. WAPLE,
Secretary.

Part 0 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

1. In § 0.31, a new paragraph (m) is added, to read as follows:

§ 0.31 Functions of the Office.

* * * * *

(m) To develop and initially implement a system of decentralized frequency management.

2. In § 0.32, a new paragraph (f) is added, to read as follows:

§ 0.32 Units in the Office.

* * * * *

(f) Spectrum Management Task Force.

3. A new § 0.38 is added, to read as follows:

§ 0.38 Spectrum Management Task Force.

The Spectrum Management Task Force is responsible, in coordination with the respective bureaus which have primary responsibility for the radio services involved, for development of a Spectrum Management Program designed to provide more effective and efficient use of the radio spectrum through the introduction of system engineering concepts and decentralized frequency assignment techniques; makes recommendations to

[1] Commissioner Johnson concurring in the result.

the Chairman and Commission on policies, rules and regulations concerning decentralized frequency management; carries out research and development projects and systems engineering projects required to implement the Spectrum Management Program; develops data banks and data processing systems for decentralized frequency managment; and establishes and operates regional spectrum management centers.

[FR Doc.71-1666 Filed 2-5-71;8:46 am]

[No. 58468]

PART 21—DOMESTIC PUBLIC RADIO SERVICES (OTHER THAN MARITIME MOBILE)

PART 23—INTERNATIONAL FIXED PUBLIC RADIOCOMMUNICATION SERVICES

PART 25—SATELLITE COMMUNICATIONS

Miscellaneous Amendments

Order. 1. Preparatory to the reprinting of the revised edition of Volume VII of the Commission's rules and regulations, numerous editorial changes were made in Parts 21, 23, and 25. The majority of the changes involve substituting the term "hertz (Hz)" for the term "cycles per second (c/s)" in its various forms.

2. Adoption of these changes is desirable in order to clarify the rules, make them uniform as to usage and terminology, delete obsolete material, and otherwise improve them from an editorial standpoint. Since the changes are editorial in nature, the prior notice and effective date provisions of section 4 of the Administrative Procedure Act (5 U.S.C. 539) are not applicable. The changes below are included in the revised edition of Volume VII currently on sale at the Superintendent of Documents, U.S. Government Printing Office.

3. *Accordingly, it is ordered,* Pursuant to authority contained in sections 4(i), 5(d), and 303(r) of the Communications Act of 1934, as amended, and § 0.261(a) of the Commission's rules and regulations, that effective February 10, 1971, Parts 21, 23, and 25 are amended as set forth below.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; 47 U.S.C. 154, 155, 303)

Adopted: January 28, 1971.

Released: January 29, 1971.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] BEN F. WAPLE,
Secretary.

Chapter I of Title 47 of the Code of Federal Regulations is amended with respect to Parts 21, 23, and 25. The terms listed below are substituted throughout:

GHz for Gc/s gigahertz for gigacycles.
Hz for c/s hertz for cycles per second.
kHz for kc/s kilohertz for kilocycles.
MHz for Mc/s megahertz for megacycles.

The following additional changes are also made:

A. In Part 21—Domestic Public Radio Services (Other than Maritime Mobile):

1. In § 21.14 (i) and (j), the address "Director, Telecommunications and Electronics Branch, Department of Transport, Ottawa, Ontario, Canada," is corrected to read "Director, Telecommunications Regulations Branch, Department of Communications, Ottawa, Ontario, Canada."

2. Section 21.101(a) is amended by substituting "2,110 to 2,200" for "2,110 to 2,220" in the first column of the chart under the heading "Frequency range (MHz)".

3. In § 21.109, the parenthetical reference at the end of paragraph (b) is amended to read, "(c.f. §§ 21.15(g) and 21.121(c))".

4. In § 21.120(b), "Part C" is deleted at the end of the second sentence.

5. In § 21.121 ,the parenthetical reference at the end of paragraph (d) is amended to read, "(c.f. §§ 21.15 and 21.121(c))".

6. In § 21.509, the parenthetical reference at the end of paragraph (h) is amended to read, "(See § 21.14 (i) and (j))".

7. In § 21.519(a) reference to § 17.3 in the first sentence is corrected to read "§ 17.7".

B. In Part 23—International Fixed Public Radiocommunication Services:

1. In § 23.53, the following proviso is added at the end of introductory paragraph (a): "* * * *Provided, however,* That the licensee, upon institution of addressed press service to any point, shall promptly notify the Commission of the following:".

[FR Doc.71-1667 Filed 2-5-71;8:46 am]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Administration, Department of Transportation

[Docket No. 10822; Amdt. 39-1154]

SUBCHAPTER C—AIRCRAFT

PART 39—AIRWORTHINESS DIRECTIVES

British Aircraft Corp. Viscount Models 744, 745D, and 810 Series Airplanes

A failure of the left elevator servo tab system has occurred on a British Aircraft Corp. Viscount Model airplane. The failure was caused by a complete fracture of the shank of spigot bracket, P/N 70120-367, which attaches the elevator spring service tab system bellcrank to the left elevator torque tube. In view of the serious consequences of such a failure and since this condition is likely to exist or develop in other airplanes of the same type design, an Airworthiness Directive (AD) is being issued to require repetitive inspections of the bracket and replacement of defective brackets.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedures thereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (14 CFR 11.89), § 39.13 of Part 39 of the Federal Aviation Regulations is amended by adding the following new airworthiness directive.

BRITISH AIRCRAFT CORP. Applies to Viscount Model 744, 745D, and 810 Series airplanes.

Compliance required as indicated.

To prevent failure of the elevator spring servo tab control mechanism accomplish the following:

(a) Within the next 50 hours' time in service after the effective date of this AD, unless already accomplished within the last 1,000 hours' time in service before the effective date of this AD, visually inspect the shank of spigot bracket, P/N 70120-367, which attaches the elevator spring service tab system bellcrank to the left elevator torque tube, for evidence of corrosion.

(b) Before the accumulation of 12,000 hours' time in service on spigot bracket, P/N 70120-367, or within the next 100 hours' time in service after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 12,000 hours' time in service from the last inspection or replacement, remove spigot bracket, P/N 70120-367 from the airplane, and either (1) replace the spigot bracket with a new bracket of the same part number, or (2) visually inspect the shank of the spigot bracket for evidence of corrosion, and if no evidence of corrosion is found inspect the shank for cracks using the magnetic flow detection saturation method in accordance with British Aircraft Corp. wire SS922V dated January 25, 1970, or an FAA-approved equivalent.

(c) If evidence of corrosion is found during the inspections required by paragraph (a) and subparagraph (b)(2) of this AD, or cracks are found during the inspections required by subparagraph (b)(2) of this AD, before further flight, replace the spigot bracket with a new bracket of the same part number.

(d) Operators who have not kept records of hours' time in service on individual spigot brackets, P/N 70120-367, shall substitute airplane hours' time in service in lieu thereof.

NOTE. It is requested that the results, positive and negative, of the inspection required by this AD be reported, in writing, to the Chief, Aircraft Certification Staff, FAA Europe, Africa, and Middle East Region, c/o American Embassy, APO New York, NY 09667.

(Reporting approved by the Bureau of the Budget, BOB No. 04-R-174)

This amendment becomes effective February 6, 1971.

(Secs. 313(a), 601, 603, Federal Aviation Act of 1958, 49 U.S.C. 1354(a), 1421, 1423; sec. 6(c), Department of Transportation Act, 49 U.S.C. 1655(c))

Issued in Washington, D.C., on February 5, 1971.

JAMES F. RUDOLPH,
Director, Flight Standards Service.

[FR Doc.71-1776 Filed 2-5-71;10:07 am]

SUBCHAPTER F—AIR TRAFFIC AND GENERAL OPERATING RULES

[Reg. Docket No. 10803; Amdt. 95-203]

PART 95—IFR ALTITUDES

Miscellaneous Amendments

The purpose of this amendment to Part 95 of the Federal Aviation Regulations is to make changes in the IFR