

In § 71.181 (34 F.R. 4637), the Stuart, Fla., transition area is revoked.

(Sec. 307(a), Federal Aviation Act of 1958, 49 U.S.C. 1348(a); sec. 6(c), Department of Transportation Act, 49 U.S.C. 1655(c))

Issued in East Point, Ga., on October 31, 1969.

JAMES G. ROGERS,  
Director, Southern Region.

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8:48 a.m.]

[Airspace Docket No. 69-SO-130]

# PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS

## Revocation of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to revoke the Louisville, Miss., transition area.

The Louisville transition area, described in § 71.181 (34 F.R. 4637), was designated to provide controlled airspace protection for IFR operations at Louisville-Winston County Airport. Two prescribed instrument approach procedures to this airport, utilizing a proposed (private) nondirectional radio beacon, were developed.

Louisville-Winston County officials advised that the proposal to establish the nondirectional radio beacon had been abandoned. Accordingly, it is necessary to amend Part 71 of the Federal Aviation Regulations by revoking this transition area.

Since this amendment lessens the burden on the public, notice and public procedure hereon are unnecessary.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective immediately, as hereinafter set forth.

In § 71.181 (34 F.R. 4637), the Louisville, Miss., transition area is revoked.

(Sec. 307(a), Federal Aviation Act of 1958, 49 U.S.C. 1348(a); sec. 6(c), Department of Transportation Act, 49 U.S.C. 1655(c))

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JAMES G. ROGERS,  
Director, Southern Region.

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[Airspace Docket No. 69-SO-127]

# PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS

## Alteration of Control Zone and Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to alter the Orlando, Fla. (McCoy AFB), control zone and the Orlando, Fla., transition area.

The Orlando (McCoy AFB) control zone is described in § 71.171 (34 F.R. 4557) and the Orlando transition area is described in § 71.181 (34 F.R. 4637). In the descriptions, references are made to

the McCoy AFB LOM. Since the compass locator, which is collocated with the outer marker, will be decommissioned, effective January 29, 1970, it is necessary to alter the descriptions to delete references to the LOM and make reference to the OM.

Since these amendments are editorial in nature, notice and public procedure hereon are unnecessary and action is taken herein to amend the descriptions accordingly.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.M.T., January 29, 1970, as hereinafter set forth.

In § 71.171 (34 F.R. 4557), the Orlando, Fla. (McCoy AFB), control zone and in § 71.181 (34 F.R. 4637), the Orlando, Fla., transition area are amended as follows: " \* \* \* LOM \* \* \* " is deleted and " \* \* \* OM \* \* \* " is substituted therefor, wherever it appears.

(Sec. 307(a), Federal Aviation Act of 1958, 49 U.S.C. 1348(a); sec. 6(c), Department of Transportation Act, 49 U.S.C. 1655(c))

Issued in East Point, Ga., on November 4, 1969.

JAMES G. ROGERS,  
Director, Southern Region.

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8:49 a.m.]

[Airspace Docket No. 69-SO-90]

# PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS

## Designation of Transition Area

On September 24, 1969, a notice of proposed rule making was published in the FEDERAL REGISTER (34 F.R. 14737), stating that the Federal Aviation Administration was considering an amendment to Part 71 of the Federal Aviation Regulations that would designate the Clarksdale, Miss., transition area.

Interested persons were afforded an opportunity to participate in the rule making through the submission of comments. All comments received were favorable.

Subsequent to publication of the notice, the geographic coordinate (lat. 34°17'45" N., long. 90°30'50" W.) for Fletcher Field was obtained from Coast and Geodetic Survey. Also, it was determined that the word "area" was inadvertently omitted from the extensions predicated on the 010° and 163° bearings from Clarksdale RBN. It is necessary to alter the description by inserting the geographic coordinate for the airport and appropriately inserting the word "area."

Since these amendments are editorial in nature, notice and public procedure hereon are unnecessary and action is taken herein to alter the description accordingly.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.M.T., February 5, 1970, as hereinafter set forth.

In § 71.181 (34 F.R. 4637), the following transition area is added:

CLARKSDALE, MISS.

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Fletcher Field (lat. 34°17'45" N., long. 90°30'50" W.); within 3 miles each side of the 010° and 163° bearings from the Clarksdale RBN (lat. 34°17'33" N., long. 90°30'57" W.), extending from the 6.5-mile radius area to 8.5 miles north and south of the RBN.

(Sec. 307(a), Federal Aviation Act of 1958, 49 U.S.C. 1348(a), sec. 6(c), Department of Transportation Act, 49 U.S.C. 1655(c))

Issued in East Point, Ga., on November 4, 1969.

JAMES G. ROGERS,  
Director, Southern Region.

[F.R. Doc. 69-13474; Filed, Nov. 12, 1969;  
8:49 a.m.]

# Title 16—COMMERCIAL PRACTICES

## Chapter I—Federal Trade Commission

SUBCHAPTER E—RULES, REGULATIONS, STATEMENT OF GENERAL POLICY OR INTERPRETATION AND EXEMPTIONS UNDER THE FAIR PACKAGING AND LABELING ACT

## PART 500—REGULATIONS UNDER SECTION 4 OF THE FAIR PACKAGING AND LABELING ACT

### Confirmation of Effective Date of Order

In the matter of amending § 500.3 (c) and (d) by inserting the words "packaged and labeled" immediately before the words "consumer commodity" where the latter appears in each paragraph, and amending § 500.16 by inserting "thirds" in the listing of common fractions which may be used to express linear measurements in yards and feet:

Pursuant to the provisions of the Fair Packaging and Labeling Act (sections 4, 6, 80 Stat. 1297, 1299, 1300; 15 U.S.C. 1453, 1454, 1455), notice is given that no objections were filed in the above-identified matter published in the FEDERAL REGISTER of September 24, 1969 (34 F.R. 14730). Accordingly, the October 24, 1969 effective date of the amendments to §§ 500.3 (c) and (d) and 500.16 is confirmed.

Issued: November 7, 1969.

By direction of the Commission.

[SEAL] JOSEPH W. SHEA,  
Secretary.

[F.R. Doc. 69-13504; Filed, Nov. 12, 1969;  
8:51 a.m.]

## PART 500—REGULATIONS UNDER SECTION 4 OF THE FAIR PACKAGING AND LABELING ACT

### Measurement of Container Type Commodities, How Expressed

In the matter of amending Part 500 by the addition of a new § 500.15a prescribing the manner of expressing the measurement of container type commodities:



Pursuant to the provisions of the Fair Packaging and Labeling Act (sections 4, 6, 80 Stat. 1297, 1299, 1300; 15 U.S.C. 1453, 1454, 1455), notice is given that no objections were filed in the above-identified matter published in the *FEDERAL REGISTER* of September 24, 1969 (34 F.R. 14731). Accordingly, the February 1, 1970, effective date of the new § 500.15a is confirmed.

Issued: November 7, 1969.

By direction of the Commission.

[SEAL] JOSEPH W. SHEA,  
Secretary.

[F.R. Doc. 69-13503; Filed, Nov. 12, 1969;  
8:51 a.m.]

## Title 17—COMMODITY AND SECURITIES EXCHANGES

### Chapter II—Securities and Exchange Commission

[Release Nos. 33-5018 and 34-8733]

#### PART 231—INTERPRETATIVE RE- LEASES RELATING TO THE SECU- RITIES ACT OF 1933 AND GEN- ERAL RULES AND REGULATIONS THEREUNDER

#### PART 241—INTERPRETATIVE RE- LEASES RELATING TO THE SECUR- ITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULA- TIONS THEREUNDER

##### Sale and Distribution of Whisky Warehouse Receipts

The Securities and Exchange Commission today called attention to the applicability of the Federal securities laws to the sale and distribution of whisky warehouse receipts in areas subject to the jurisdiction of the United States. The Commission pointed out that the promotion and sale of such receipts may involve an offering of a security in the form of an investment contract within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, and that any public offering of any such securities must comply with the registration and prospectus requirements of the Securities Act, unless an exemption therefrom is available, and must comply with the antifraud provisions of the Securities Act and the Securities Exchange Act and the regulations thereunder.

Recently, the public promotion and distribution of whisky warehouse receipts has been increasing in the United States. In most cases the whisky warehouse receipts offered have related to unblended whisky, usually unblended Scotch whisky being aged in a bonded warehouse in Scotland. The production of Scotch whis-

ky involves distilling, aging, and blending. The blenders, who blend many varieties of aged whisky to arrive at their final product, are frequently unable to finance the purchase of all their needs from distillers because of the burden of financing the long aging process and because of the risks associated with changes in the whisky as it mellows. The aging process is a fundamental part of the production process. Freshly distilled Scotch whiskies vary considerably and change as they age, and blenders' needs change as public tastes change; consequently the need for a particular whisky cannot be determined until it is ready for blending. In order to finance the risks involved in the final production of a blended whisky, whisky warehouse receipts are sold to persons and institutions. Generally, the receipt covers casks of whisky which are contained in one or more warehouses, and the arrangement under which the whisky warehouse receipt is sold to the investor-purchaser generally contemplates that the whisky will continue to be stored until it is aged and that it will eventually be sold for him to the blenders who will use it to blend other whiskies to produce the final product.

The purchaser of the whisky warehouse receipt is not being offered or sold such receipts with a view to acquiring and taking possession of the whisky. Rather, the purchaser in these cases is making an investment under an arrangement which contemplates that others will perform services which will increase the value of the whisky and will also eventually sell the whisky under circumstances which are expected to result in a profit to the purchaser-investor.

In *S.E.C. v. W. J. Howey Co.*, 328 U.S. 293, 301 (1946), the Supreme Court stated that the test of whether a security is being offered "is whether the scheme involves an investment of money in a common enterprise with profits to come solely from the efforts of others. If that test be satisfied, it is immaterial whether the enterprise is speculative or non-speculative, or whether there is a sale of property with or without intrinsic value \* \* \*. The statutory policy of affording broad protection to investors is not to be thwarted by unrealistic and irrelevant formulae." In *Howey* the Supreme Court noted that the Commission has followed the same definition in *In re National Resources Corporation*, 8 S.E.C. 635 (1941). The Commission there stated that "transactions which, in form, appear to involve nothing more than the sale of real estate, chattels or services, have been held to be investment contracts where, in substance, they involve the laying out of money by the investor on the assumption and expectation that the investment will return a profit without any active effort on his part, but

rather as the result of the efforts of someone else." 8 S.E.C. at 637.<sup>1</sup>

The anti-fraud provisions of the Federal securities laws, including section 17(a) of the Securities Act and section 10(b) and Rule 10b-5 (17 CFR 240.10b-5) under the Securities Exchange Act, make it unlawful, in connection with the purchase or sale of a security, to make misstatements or misleading omissions of material facts, and prohibit other fraudulent and deceptive practices. The anti-fraud provisions apply to advertisements, literature and other statements and representations made in connection with the offer and sale of securities, and particular attention is called to these provisions in view of the exaggerated claims made in some of the advertisements and other material used to promote sales of whisky warehouse receipts.

It should also be noted that persons engaged in the business of buying or selling investment contracts taking the form of whisky warehouse receipts as agents for others, or in the business of buying and selling such securities as principal for their own account, would be brokers or dealers within the meaning of the Securities Exchange Act of 1934, and would generally be required to be registered as such with the Commission under the provisions of section 15 of the Act. Such a broker or dealer would be subject also to other regulatory provisions, including the Commission's Rule 15c3-1 (17 CFR 240.15c3-1), which imposes net capital requirements on brokers and dealers.

Persons engaging in the sale of whisky warehouse receipts who have any questions concerning the applicability of the Federal securities laws to their activities should consult the nearest regional office of the Commission.

By the Commission, November 4, 1969.

[SEAL] ORVAL L. DUBOIS,  
Secretary.

[F.R. Doc. 69-13455; Filed, Nov. 12, 1969;  
8:47 a.m.]

<sup>1</sup> This is not the first time that the Commission has been concerned with the sale of whisky warehouse receipts in the context of investment contracts. In two related cases, *Penfield Co. v. S.E.C.*, 143 F.2d 746 (9th Cir. 1944), and *S.E.C. v. Bourbon Sales Corp.*, 47 F. Supp. 70 (W.D. Ky., 1942), subpoenas issued by the Commission were enforced by the courts despite respondents' objections that no securities were involved. The respondents sold bourbon whisky warehouse receipts to investors and then, in exchange for the receipts, offered them contracts under which the respondents would bottle and sell the whisky for the investor with the respondents keeping a percentage of the profit. The court in *Penfield* stated: "These contract provisions and representations, as well as the fact that the contract-holders, being ordinary investors and not liquor dealers, would not have the facilities or the necessary Federal and State liquor licenses to take the whisky out of bond and dispose of it, make it clear that they must look entirely to the efforts of the promoters to make their investment a profitable one, the criterion in our opinion in *Atherton v. United States* \* \* \* [128 F.2d 463 (9th Cir. 1942)] at page 465." 143 F.2d at 751.



## Title 21—FOOD AND DRUGS

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

#### SUBCHAPTER C—DRUGS

#### PART 141c—CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

#### PART 146c—CERTIFICATION OF CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE (OR TETRACYCLINE-) CONTAINING DRUGS

#### PART 148n—OXYTETRACYCLINE

#### Certain Tetracycline-Nystatin, Oxytetracycline-Nystatin, and Demethylchlortetracycline-Nystatin Combination Preparations for Oral Use in Humans

In the FEDERAL REGISTER of April 2, 1969 (34 F.R. 6007), the Commissioner of Food and Drugs announced the conclusions of the Food and Drug Administration following evaluation of reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following preparations:

A. Combination drugs containing tetracycline, tetracycline hydrochloride, or tetracycline phosphate complex with nystatin:

1. Mysteclin-V Capsules; E. R. Squibb & Sons, Inc., Georges Road, New Brunswick, N.J. 08903.

2. Terrastatin for Oral Suspension; Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017.

3. Terrastatin Capsules; Chas. Pfizer & Co., Inc.

4. Comycin Half-Strength Capsules; The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002.

5. Comycin Capsules; The Upjohn Co.

6. Achrostatin V for Oral Suspension; Lederle Laboratories, Division of American Cyanamid Co., West Middletown Road, Pearl River, N.Y. 10965.

7. Achrostatin V Capsules; Lederle Laboratories, Division of American Cyanamid Co.

B. Combination drugs containing oxytetracycline and nystatin:

1. Terrastatin for Oral Suspension; Chas. Pfizer & Co., Inc.

2. Terrastatin Capsules; Chas. Pfizer & Co., Inc.

C. Combination Drugs containing demethylchlortetracycline and nystatin:

1. Declostatin for Oral Suspension; Lederle Laboratories, Division of American Cyanamid Co.

2. Declostatin Capsules; Lederle Laboratories, Division of American Cyanamid Co.

The Academy evaluated these drugs as ineffective as fixed combinations for simultaneous antimicrobial therapy and

monilial prophylaxis and found that adequate documented evidence is lacking that the fixed combinations are useful during therapy in preventing clinical disease due to monilial superinfection. The Food and Drug Administration concurred with the views expressed by the Academy and concluded that substantial evidence is lacking that each of these combination drugs will have the effect it purports or is represented to have.

All interested persons who might be adversely affected by removal of drugs containing any of the above-listed combinations from the market were invited to submit within 30 days, any pertinent data bearing on the proposal to amend the antibiotic drug regulations to delete from the list of drugs acceptable for certification, those that contain the above-listed antibiotic combinations.

Lederle Laboratories submitted responses to the announcement which have been reviewed and found to contain no new clinical data. The Food and Drug Administration concludes that the material submitted does not provide substantial evidence of effectiveness of such combination drugs.

In addition to the above-listed products, for which the conditions of certification are described in §§ 141c.224, 141c.225, 141c.229, 141c.236, 141c.259, 141c.263, 146c.224, 146c.236, 146c.259, 146c.263, 148n.9 and 148n.10, other sections, §§ 141c.271, 146c.225, 146c.229, and 146c.271, described the conditions for certification of other oral dosage forms of such combinations. Preparations currently marketed under these regulations in addition to those listed above are:

1. Tetrex-F Capsules (tetracycline phosphate complex-nystatin) and Tetrex-F for Oral Suspension (tetracycline-nystatin); Bristol Laboratories, Division of Bristol-Myers Co., Thompson Road, Syracuse, N.Y. 13201.

2. Declostatin 300 Tablets (demethylchlortetracycline-nystatin); Lederle Laboratories, Division of American Cyanamid Co.

The data submitted in support of these preparations, though not evaluated by the National Academy of Sciences—National Research Council, have been reviewed by the Food and Drug Administration and have been found to lack substantial evidence that the fixed combinations will have the effect they purport or are represented to have.

Accordingly, the Commissioner of Food and Drugs concludes (1) that the regulations for the certification of antibiotic drugs should be amended as follows to delete the above-listed antibiotic combinations of oral dosage forms for human use from the list of drugs acceptable for certification and (2) that all outstanding certificates heretofore issued for such combination drugs should be revoked.

Therefore, pursuant to the provisions of the Federal Food, Drug and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 141c, 146c and 148n are

amended by repealing §§ 141c.224, 141c.225, 141c.229, 141c.236, 141c.259, 141c.263, 141c.271, 146c.224, 146c.225, 146c.229, 146c.236, 146c.259, 146c.263, 146c.271, 148n.9, and 148n.10, and all antibiotic certificates issued under those regulations are revoked.

Any person who will be adversely affected by the removal of any such drugs from the market may file, within 30 days after publication hereof in the FEDERAL REGISTER, objections to this order stating reasonable grounds and requesting a hearing on such objections. A statement of reasonable grounds for a hearing (1) should identify the claimed errors in the National Academy of Sciences—National Research Council's evaluation and the Administration's conclusions as to the effectiveness of the combination drug and (2) should identify any adequate and well-controlled investigations on the basis of which it reasonably could be concluded that the drug would have the effectiveness claimed for its intended uses. Objections should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, and may be accompanied by a memorandum or brief in support thereof.

If objections accompanied by reasonable grounds are received, the Commissioner will promptly announce a hearing. If a hearing is scheduled, it will be held under the provisions of section 507 (f) of the Federal Food, Drug, and Cosmetic Act.

**Effective date.** This order shall become effective 40 days after its date of publication in the FEDERAL REGISTER unless stayed by the filing of proper objections. The Commissioner will announce in the FEDERAL REGISTER whether or not requests for hearing with reasonable grounds have been received during the 30-day period. At that time the Commissioner will specify how the outstanding stocks of the affected drugs are to be handled.

(Secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357)

Dated: November 4, 1969.

HERBERT L. LEY, JR.,

Commissioner of Food and Drugs.

[F.R. Doc. 69-13425; Filed, Nov. 12, 1969; 8:46 a.m.]

## Title 22—FOREIGN RELATIONS

### Chapter I—Department of State

[Departmental Reg. 108.612]

#### PART 41—VISAS: DOCUMENTATION OF NONIMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

#### Automatic Revalidation of Nonimmigrant Visas in Certain Cases

Part 41, Chapter I, Title 22 of the Code of Federal Regulations is being amended to provide for automatic revalidation of