

May 28, 1968

could be expedited for those identified as derived from animals that did not originate in such locations.

This amendment would require that identifying marks (such as ear tags, back tags, implants, etc.) be related to the carcass until a final post-mortem inspection is completed. One procedure would be to place identifying marks in a clean plastic bag and attach to the carcass. Modification of this or other adequate procedures which the meat industry would use to meet the intent of the regulations would be acceptable.

When indicated by post-mortem findings, these identifying features could then be reviewed to develop information concerning the animal which would aid in making a disposition or deciding if further testing is desirable.

Any person who wishes to submit written data, views, or arguments concerning the proposed amendment may do so, by filing them, in duplicate, with the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250, within 60 days after the date of publication of this notice in the FEDERAL REGISTER. All written submissions made pursuant to this notice will be made available for public inspection at times and places and in a manner convenient to the public business (7 CFR 1.27(b)).

Done at Washington, D.C., this 22d day of May 1968.

R. K. SOMERS,
Deputy Administrator,
Consumer Protection.

[F.R. Doc. 68-6296; Filed, May 27, 1968; 8:46 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
[21 CFR Part 130]
NEW DRUGS

Drugs, in Finished Dosage Form, for Human Use Previously Cleared Through New-Drug Procedures for Which New-Drug Applications Are Not Now Required as Condition for Marketing; Proposed Listing of Metyrapone and Metyrapone Ditartrate

To inform interested persons, especially manufacturers and distributors of drugs, of the policies and interpretations of the Food and Drug Administration resulting from the review of the effectiveness of drugs that were cleared through the new-drug procedures (21 U.S.C. 355) between 1938 and October 10, 1962, on the basis of safety (see FEDERAL REGISTER notice of July 9, 1966; 31 F.R. 9426) and related policy determinations concerning the current new-drug status of such drugs, it is proposed that new sections be added to Part 130 as set forth below including a proposed listing of metyrapone and metyrapone ditartrate as a

drug for human use that does not now require an approved new-drug application.

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502(a), (f), 505, 701(a), 52 Stat. 1041, 1050-53, 1055, as amended 76 Stat. 781-84; 21 U.S.C. 321(p), 352(a), (f), 355, 371(a)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that Part 130 be amended by adding thereto a new Subpart D containing two new sections, as follows:

Subpart D—Human-Use Drugs (in Finished Dosage Form) Previously Cleared Through New-Drug Procedures for Which Approved New-Drug Applications Are Not Now Required as a Condition for Marketing

§ 130.301 Drugs for human use that do not now require an approved new-drug application.

(a) Drugs introduced into the market through the new-drug procedures (21 U.S.C. 355) between 1938 and 1962 have been subject to reevaluation to determine if they are effective as well as safe for their recommended uses pursuant to section 107 of the Kefauver-Harris Act (Public Law 87-781; 76 Stat. 788-89) enacted October 10, 1962. Based on the reevaluation of these drugs, the Food and Drug Administration will regard under specific conditions some of these drugs as no longer new drugs as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act as amended by the Kefauver-Harris Act.

(b) Any drug introduced through the new-drug procedures or marketed without new-drug clearance may be listed in § 130.302 as not now requiring an approved new-drug application for marketing when it is determined by the Commissioner that such drug, adequately identified and meeting appropriate standards, is generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling and that it has been used to a material extent and for a material time under such conditions.

(c) The conditions under which specified drugs could be listed as not now requiring an approved new-drug application will be proposed by the Commissioner in the FEDERAL REGISTER, on his own initiative or on behalf of any interested person, and written comments will be invited. After considering all available data, the Commissioner will issue an order in the FEDERAL REGISTER providing for or ruling against such listing. Proposals submitted to the Commissioner by an interested person may be refused by written notice from the Commissioner if the proposal is not supported by reasonable grounds.

(d) Proposals by interested persons for listing a drug as not now requiring an approved new-drug application shall include the drug's labeling or proposed labeling, a full statement of its composition, a showing that the drug has been

used to a material extent and for a material time under such conditions, and a statement of reasonable grounds for classifying the drug as generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in its labeling.

(e) If the Commissioner finds that new evidence of clinical experience or other information regarding the safety or effectiveness of a drug listed in § 130.302(b) invalidates a prior conclusion that a drug is generally recognized by qualified experts as safe and effective for use under the conditions set forth in such a regulation, he shall:

(1) After furnishing public notice of the proposal in the FEDERAL REGISTER and opportunity for comment thereon:

(i) Promulgate a revision of the conditions set forth in the regulation to establish conditions under which he finds that the drug is generally recognized by qualified experts as safe and effective; or

(ii) Promulgate an order revoking such listing of the drug when he finds that the drug has not been used to a material extent or for a material time under conditions of use that are generally recognized by qualified experts as safe and effective; or

(2) Promulgate an order immediately revoking such listing of the drug if:

(i) The Secretary has suspended the approval of a new-drug application for such drug immediately on a finding that there is an imminent hazard to the public health, as provided in section 505(e) of the act; or

(ii) The Commissioner finds that there is an imminent hazard to the public health and that no approval of a new-drug application is in effect for such drug.

(f) The listing of drugs in § 130.302(b) does not apply to drugs of different composition or labeling from that stated therein, and the marketing or promoting of a drug for use under conditions contrary to or inconsistent with the stated conditions may result in regulatory proceedings.

§ 130.302 List of drugs for human use that do not now require an approved new-drug application.

(a) An approved new-drug application is not now required for the finished dosage form of the drugs for human use listed in paragraph (b) of this section provided that all of the following conditions are met:

(1) *General labeling requirements.* All labeling and advertising of the drug prescribes, recommends, or suggests its use only under the conditions set forth in the specific regulation on the drug in paragraph (b) of this section.

(2) *General composition and product requirements.* (1) The active ingredients of the drug correspond completely, qualitatively and quantitatively, with the composition stated in the specific regulation in paragraph (b) of this section. The drug may contain suitable inactive ingredients only if they comply with all of the following conditions:

PROPOSED RULE MAKING

panied by a memorandum or brief in support thereof.

Dated: May 20, 1968.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 68-6307; Filed, May 27, 1968;
8:47 a.m.]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Parts 61, 91]

[Docket No. 8284; Notice 67-31]

INSTRUMENT FLIGHT TESTS, FLIGHT INSTRUCTION, AND SIMULATED INSTRUMENT FLIGHT

Use of Partial Dual Control Aircraft; Withdrawal of Proposed Rule Making

The purpose of this notice is to withdraw Notice No. 67-31 (32 F.R. 10660; July 20, 1967) in which the FAA proposed to amend Parts 61 and 91 of the Federal Aviation Regulations to permit the use of single yoke and other partial dual control aircraft for flight instruction and simulated instrument flight where the flight instructor or safety pilot has immediate and unobstructed access to all essential controls, including the power, pitch, roll, and heading controls.

The proposed amendment was based in large part on experience gained under exemptions issued to the Aircraft Owners and Pilots Association Foundation, which indicated that fully functioning dual controls in aircraft would not appear to be necessary to safely conduct flight instruction and simulated flight under certain specified conditions.

However, upon further evaluating the proposal in the light of comments received and related safety considerations, the FAA has determined that rule-making action as proposed is not appropriate for reasons of safety and that Notice 67-31 should be withdrawn.

Withdrawal of this notice constitutes only such action, and does not preclude the FAA from issuing other notices in the future or commit the FAA to any course of action in the future.

In consideration of the foregoing, the notice of proposed rule making published in the FEDERAL REGISTER (32 F.R. 10660; July 20, 1967) and circulated as Notice 67-31, is hereby withdrawn.

This withdrawal is issued under the authority of sections 313(a) and 601 of the Federal Aviation Act of 1958 (49 U.S.C. 1354, 1421).

Issued in Washington, D.C., on May 21, 1968.

R. S. SLIFF,
Acting Director,
Flight Standards Service.

[F.R. Doc. 68-6282; Filed, May 27, 1968;
8:46 a.m.]

CIVIL AERONAUTICS BOARD

[14 CFR Part 207]

[Docket No. 19757; EDR-139]

CHARTER TRIPS AND SPECIAL SERVICES

Charters From Direct Air Carriers in Emergency Situations and for Car- riage of Company Personnel and Property

MAY 23, 1968.

Notice is hereby given that the Civil Aeronautics Board has under consideration a proposed amendment to Part 207 of the Economic Regulations which would permit direct air carriers to charter aircraft to supplemental and other direct air carriers for commercial traffic in cases of emergency or solely for the transportation of company personnel or company property.

The principal features of the proposed amendment are further described in the explanatory statement. The amendment is proposed under the authority of sections 204(a) and 401 of the Federal Aviation Act of 1958, as amended (72 Stat. 743 and 754 (as amended by 76 Stat. 143); 49 U.S.C. 1324 and 1371).

Interested persons may participate in the proposed rule making through submission of twelve (12) copies of written data, views, or arguments pertaining thereto, addressed to the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. All relevant matter received on or before June 27, 1968, will be considered by the Board.

Upon receipt by the Board, copies of the above communications will be available for examination by interested persons in the Docket Section of the Board, Room 712, Universal Building, 1825 Connecticut Avenue NW., Washington, D.C.

By the Civil Aeronautics Board.

[SEAL] HAROLD R. SANDERSON,
Secretary.

Explanatory statement. Under subparagraph (1) of the definition of "Charter trip" in § 207.1 of the Board's economic regulations there is no provision permitting direct air carriers to charter aircraft from other direct air carriers for the transportation of commer-

cial traffic in emergency situations for the transportation of company or company property. However, charters can be permitted by the Board in its discretion upon the filing of a request for exemption.

Trans International Airline (TIA) has filed a petition 19757 to amend § 207.1 to permit air carriers thereunder to charter aircraft to supplemental and other direct air carriers for the transportation of commercial traffic in cases of emergency or solely for the transportation of company personnel or property of a supplemental or direct air carrier. Similar provisions are contained in other regulations of the Board: § 208.3(s) (2) (i) (a) and (ii) (a) (1) and (2) (1) applicable to supplemental air carriers, § 212.1(a) (5) applicable to foreign air carriers, § 214.2(b) (1) (i) applicable to foreign air carrier charter authority only, and § 214.2(b) (1) (i) applicable to supplemental air carriers.

TIA asserts that, because of such a provision in several instances have occurred in emergencies, supplemental air carriers have been required to purchase additional transportation for moderate group charter passengers is alleged to have resulted in an extra cost to the supplemental air carriers and considerable delay to the passengers.

Accordingly, since a similar provision is contained in all other charters, and since its absence from the regulations may cause unnecessary hardship to supplemental and other direct air carriers and charter passengers as well as administrative burden of last-minute exemption requests, the Board proposes to amend the definition of "trip" in section 207.1 to permit direct air carriers to charter supplemental and other direct air carriers for the transportation of commercial traffic in emergency situations for the transportation of company personnel and company property.

Proposed rule. It is proposed to amend Part 207 of the Economic Regulations (14 CFR Part 207) by modifying paragraph (1) of the definition of "trip" in § 207.1 to read as follows:

* * * * *

(1) By a person for his own use, including a direct air carrier when aircraft is engaged solely for the transportation of company personnel or company property, or in cases of emergency or solely for the transportation of commercial traffic).

* * * * *

[F.R. Doc. 68-6316; Filed, May 27, 1968;
8:47 a.m.]