

Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Curtis Jackson, ACE-120A, Atlanta Aircraft Certification Office, 1075 Inner Loop Road, College Park, Georgia 30337, Telephone (404) 763-7407.

SUPPLEMENTARY INFORMATION: AD 83-14-07, Amendment 39-4686, (48 FR 32553, 32554) applicable to Piper Models PA-60-600 (Aerostar 600), PA-60-601 (Aerostar 601), PA-60-601P (Aerostar 601P) and PA-60-602P (Aerostar 602P) airplanes prohibits use of wing flaps for all operations and limits the aft CG to 166.0 inches. Subsequent to the issuance of this AD, additional data became available to the FAA which showed that when an aft CG limit of 163.0 inches is used, the airplane is controllable during power on stalls with wing flaps extended. Therefore, the FAA is revising AD 83-14-07 by adding an alternate means of compliance which limits the aft CG to 163.0 inches and does not include the prohibition on use of flaps. This amendment provides an option which may be used at the operator's discretion. It imposes no additional burden on any person and is relieving in nature. Therefore, notice and public procedure hereon are unnecessary and not in public interest and good cause exists for making this Amendment effective in less than 30 days.

List of Subjects of 14 CFR 29

Aviation Safety, Aircraft.

Adoption to the Amendment

Accordingly and pursuant to the authority delegated to me by the Administrator, AD 83-14-07, Amendment 39-4686, (48 FR 32553, 32554) § 39.13 of the Federal Aviation Regulations (14 CFR 39.13) is revised as follows:

(1) Redesignate existing paragraph (b) and subparagraph (1) under paragraph (a).

(2) Add the word "or" following the new subparagraph (a)(1).

(3) Add a new paragraph (b) which reads as follows:

(b) Revise the aft CG limit in the Limitation Section of the applicable Airplane Flight Manual (AFM) or Pilot's Operating Handbook (POH) by obliterating or marking overall existing aft CG limitations numbers and inserting 163.0 inches.

This amendment becomes effective on August 31, 1983.

(Secs 313(a), 601 and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449 January 12, 1983); Sec. 11.89 of the Federal Aviation Regulations (14 CFR Sec. 11.89))

Note.—The FAA has determined that this document involves an amendment that is

relieving in nature and does not impose any additional burden on any persons. Therefore, (1) it is not a major rule under Executive Order 12291, and (2) it is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). Because its anticipated impact is so minimal, it does not warrant preparation of a regulatory evaluation. I certify it will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act because it is relieving in nature and because it involves few, if any, small entities.

Issued in Kansas City, Missouri on August 26, 1983.

John E. Shaw,
Acting Director, Central Region.

[FR Doc 83-24030 Filed 8-29-83; 2:54 pm]

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14 CFR Part 71

[Airspace Docket No. 83-AWA-12]

Alteration of VOR Federal Airways; Albuquerque, NM

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correction to final rule.

SUMMARY: To enhance the traffic flow within the Albuquerque Air Route Traffic Control Center (ARTCC) area, 11 VOR Federal Airway segments were amended or revoked. Inadvertently, V-83 was revoked between Corona and Otto, NM. This action reestablishes that airway segment.

EFFECTIVE DATE: September 29, 1983.

FOR FURTHER INFORMATION CONTACT:

Boyd V. Archer, Airspace and Air Traffic Rules Branch (AAT-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 426-8783.

SUPPLEMENTARY INFORMATION:

History

FR Doc. 83-20405 was published on July 28, 1983, (48 FR 34248) that amended or revoked 11 VOR Federal Airways in the Albuquerque ARTCC area. Inadvertently, V-83 was revoked between Corona and Otto, NM. This action reestablishes that airway segment.

List of Subjects in Part 71

VOR Federal airways.

Adoption of the Correction

Accordingly, pursuant to the authority delegated to me, FR Doc. 83-20405, as published in the **Federal Register** on July

28, 1983, (48 FR 34248) is corrected as follows:

§ 71.123 [Corrected]

V-83 [Amended]

By deleting the words " , including an E alternative INT Roswell 335° and Corona 124° radials, 85 MSL Corona"

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.69)

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Washington, D.C., on August 24, 1983.

John W. Baier,
Acting Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 83-23654 Filed 8-30-83; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 82N-0050]

Exemptions and Exclusions From the Pregnancy-Nursing Warning Required for Over-the-Counter Drugs That Are Intended for Systemic Absorption; Availability of Advisory Opinions

AGENCY: Food and Drug Administration.
ACTION: Notice; final rule-related.

SUMMARY: The Food and Drug Administration is announcing the availability of two advisory opinions providing a list of further exemptions and a list of exclusions from the general pregnancy-nursing-warning in § 201.63 (21 CFR 201.63) that is required for over-the-counter (OTC) drugs intended for systemic absorption.

ADDRESS: Written comments on the two lists and requests for single copies of the advisory opinions to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: FDA published in the *Federal Register* of December 3, 1982 (47 FR 54750), a final rule requiring a general pregnancy-nursing warning to appear in the labeling of all OTC drug products intended for systemic absorption (§ 201.63). The regulation stated that the labeling of all OTC drugs intended for systemic absorption, unless specifically exempted, would contain the following general warning: "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product." The regulation also established in § 201.63(c) two specific exemptions to the labeling requirement: (1) Drugs that are intended to benefit the fetus or nursing infant during the period of pregnancy or nursing and (2) drugs that are labeled exclusively for pediatric use. Paragraphs 5 and 6 of the preamble to the final rule (47 FR 54751-2) also discussed categories of drug products that are excluded from the labeling requirements (i.e. are beyond the scope of the regulation) because they are not intended for systemic absorption.

The effective date of the regulation was December 3, 1982, the date of publication in the *Federal Register*; however, manufacturers were given until December 5, 1983, to comply with the labeling requirement.

Since publication of the final rule, FDA has received a number of inquiries regarding application of the rule. In response to these inquiries, the agency has expanded the list of OTC drug products that are exempted from the regulation and has developed a list of drug products that are excluded. Under the provisions of § 10.85(c) (21 CFR 10.85(c)), the Commissioner of Food and Drugs considers the substance of these lists to be advisory opinions that may be relied on by manufacturers and packers of OTC human drug products. Both advisory opinions are publicly available in the Dockets Management Branch (address above).

The advisory opinion containing the list of additional drug products that are exempted from the labeling requirement includes drug products that, although

intended for systemic absorption, either would provide benefits that outweigh any possible risks they might pose to pregnant or nursing women or would not be used by pregnant or nursing women (e.g., drug products intended for men only, such as drug products used for treatment of benign prostatic hypertrophy). At a future date the agency will propose to amend the exemptions stated in § 201.63(c) to add exemptions for these drug products. Until this section is amended, the publicly available advisory opinion containing the list of exemptions is intended as the agency's formal position and may be relied on by interested firms.

The advisory opinion containing the list of OTC drug products that are excluded from the regulation is not intended to be exhaustive, but to aid firms in determining whether their products are covered by this rule. The products on this list are applied topically and/or act locally; they are not intended for systemic absorption. The agency recognizes the possibility that an OTC drug that is not intended for systemic absorption might, nevertheless, pose a risk to a fetus or nursing infant. If FDA determines, based on scientific evidence, that an excluded OTC drug poses such a risk or that there is a need for a warning for some other reason, special warnings may be required. The ongoing OTC review will help identify the need for these warnings.

The lists of additional exemptions and exclusions to the OTC pregnancy-nursing warning requirement issued as advisory opinions are available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the Dockets Management Branch. Requests for single copies of the advisory opinions may be submitted to the Dockets Management Branch and should be identified with the docket number found in brackets in the heading of this document.

Interested persons may submit written comments on these advisory opinions to the Dockets Management Branch (address above) preferably in three copies, except that individuals may submit one copy, identified with the docket number above. Such comments will be considered by the agency in determining whether amendments of or revisions to either advisory opinion are warranted. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 1983.

William R. Clark,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 83-23848 Filed 8-30-83; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 6E1837, 6E1842/R584; PH-FRL 2424-3]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals In or On Raw Agricultural Commodities; Benomyl

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for the combined residues of the fungicide benomyl and its metabolites in or on the raw agricultural commodities currants and papayas. This regulation to establish maximum permissible levels for residues of the fungicide in or on the commodities was submitted in petitions by the Interregional Research Project No. 4 (IR-4).

EFFECTIVE DATE: Effective on August 31, 1983.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Donald Stubbs, Emergency Response and Minor Use Section, Registration Division (TS-767C), Environmental Protection Agency, Rm. 716D, CM No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-1192).

SUPPLEMENTARY INFORMATION: EPA issued a notice of proposed rulemaking, published in the *Federal Register* of June 29, 1983 (48 FR 29889), which announced that the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petitions 6E1837 and 6E1842 to the Agency on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Oregon and Washington (PP 6E1837) and Florida (PP 6E1842).

These petitions requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the