commenters claimed it would cost hundreds of thousands of dollars for large companies to comply. They claimed that these costs would not be offset by any substantial gain in safety. Others claimed that the costs were not unrealistic and that protection could be provided at a cost of $25 for each man that used portable electrical tools. However, no commenter gave a supported figure.

III. *Conclusions.* An analysis of the entire record on the subject of ground-fault circuit interrupters for use on the temporary wiring on construction sites raises many questions as to the necessity for GFCI's and the need for further research. For example, the question of what the ground-fault current trip level should be has yielded various values. Some authorities recommend 5 mA ±1, others suggest values as high as 20 or 30 mA and another commenter would allow the level to be established by a testing authority. Each of these arguments has merit, yet the wide range of recommendations would suggest that further data, study, and analysis is needed on this parameter of GFCI's.

The question as to whether or not the equipment grounding technique presently required on construction sites would adequately protect employees from hazardous electrical shock, and therefore render the use of GFCI's as redundant, was not resolved. Here a comparison of the effectiveness of both equipment grounding and GFCI systems indicates that when a person's body resistance is at a low value (approximately 500 ohms) and the equipment grounding resistance is assumed to be one ohm, the equipment grounding system may not be totally effective. Yet this is the extreme case and perhaps not a very frequent one. However, when the body resistance is higher, the GFCI might be considered as a redundant and therefore unnecessary protective system.

Of the several comments received which addressed the subject of cost to implement GFCI's on the temporary wiring at construction sites, none provided substantiating data. Most commenters indicated that the cost would be high. Acceptance of this data would have to be based on various assumptions. One such assumption is that an existing temporary wiring system be completely reworked, including all new wire and electrical components such as switchgear, conduit, panel boxes, receptacles, etc. Those commenters which indicated low cost, also failed to substantiate their claims. No estimate of actual cost which could be considered valid was presented. Without this data the economic impact on the affected parties is difficult to gauge and the cost/benefit relationship of GFCI's cannot be ascertained. If in fact the high cost (31 million dollars) is correct, then perhaps this money might be expended on some other consideration which would yield greater safety at construction sites.

The number of fatalities which could have been prevented by using GFCI's on construction was submitted in data which was incomplete, inconclusive or possibly irrelevant. The data submitted varied from one fatality in over one billion manhours of construction to as many as 31 fatalities over a 4½-year period of construction work. Again, the cost/benefit relationship is difficult to gauge without accurate data to support it.

Serious questions were raised as to the reliability of GFCI's. Some commenters reported that their units would cause numerous "nuisance trips" without apparent cause. Such nuisance tripping would result in "downtime" which is understandably objectionable; and until a determination is made as to the cause of these nuisance trips, the question of the reliability of GFCI's will be difficult to answer.

Therefore, based on an analysis of the record developed up to this point, OSHA proposes to revoke the requirement that GFCI's be used on construction sites, in view of the issues discussed above and because such a requirement has not been shown to be necessary to the safety and health of employees. Such a revocation could be changed if there is a later determination that complete and accurate information is available which warrants mandatory utilization of GFCI's on construction sites.

IV. *Public participation.* Interested persons are invited to submit written data, views, and arguments concerning the proposed revocation. Comments must be postmarked before May 7, 1975, and submitted to: Docket Officer, Docket No. S–102, OSHA, Department of Labor, Room 220, 1726 M Street, NW., Washington, D.C. 20210. All written comments will be available for public inspection and copying at the above address.

Specifically, written data, views, and arguments are requested with respect to:

(1) The necessity for GFCI's in addition to existing protective measures;

(2) The experience with GFCI's required under State regulations and/or municipal codes;

(3) Injury and/or fatality statistics specifically related to the lack of GFCI's;

(4) Cost of utilizing GFCI's on temporary wiring on construction sites; and

(5) Reliability of GFCI's in terms of tripping levels.

Additionally, interested persons may file with the Docket Officer by June 6, 1975, written objections to the proposed revocation and request an informal hearing on the objections. These objections shall comply with the following:

(1) The objections must include the name and address of the objector;

(2) The objections must be postmarked by June 6, 1975;

(3) The objections must state the grounds therefor;

(4) Each objection must be separately stated and numbered; and

(5) The objections must be accompanied by a summary of the evidence proposed to be adduced at the requested hearing.

V. *Proposal.* Accordingly, pursuant to section 6(b) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1593, (29 U.S.C. 655)), section 107 of the Contract Work Hours and Safety Standards Act (83 Stat. 96; (40 U.S.C. 333)), Secretary of Labor's Order No. 12–71 (36 FR 8754), and 29 CFR Part 1911, it is proposed to amend Parts 1910 and 1926 of Title 29 of the Code of Federal Regulations as follows:

1. In 29 CFR Part 1910, § 1910.309(c) would be amended to read as follows:

§ 1910.309 National Electrical Code.

* * * * *

(c) Notwithstanding the provisions of paragraphs (a) and (b) of this section, the requirement in section 210–7 of the National Electrical Code that all 15- and 20-ampere receptacle outlets on single-phase circuits for construction sites have approved ground-fault circuit protection for personnel shall not be applicable.

2. In 29 CFR Part 1926, § 1926.400(h) would be amended to read as follows:

§ 1926.400 General Requirements.

* * * * *

(h) Notwithstanding any other provision of this part, the requirement in section 210–7 of the National Electrical Code that all 15- and 20-ampere receptacle outlets on single-phase circuits for construction sites have approved ground-fault circuit protection for personnel shall not be applicable.

(Sec. 6(b), Pub. L. 91–596, 84 Stat. 1593 (29 U.S.C. 655); sec. 107, Pub. L. 91–54, 83 Stat. 96 (40 U.S.C. 333); Secretary of Labor's Order No. 12–71, 36 FR 8754).)

Signed at Washington, D.C. this 1st day of April, 1975.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.75–8937 Filed 4–4–75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 1, 3]

LABELING FOR PRESCRIPTION DRUGS USED IN MAN

Proposed Format for Prescription Drug Advertisements

The primary objective of prescription drug labeling is to provide the essential information the practitioner needs to use the drug safely and effectively in the care of patients. After reviewing whether this objective is being met, the Commissioner of Food and Drugs has determined that significant improvements can and should be made in drug labeling. Improvement can be accomplished by revising the format now contained in § 3.74 (21 CFR 3.74), by providing standards with regard to the kind of information that must be included under each of the specific section headings, by eliminating extraneous information which can best be obtained from the published literature, by providing explicit information on indications of use, and by replacing generalities with specifics. To improve prescription drug labeling, the Commissioner of Food and Drugs is proposing regulations designating a required format and the kinds of information that shall appear under each section heading.

In proposing these regulations, the Commissioner emphasizes that the principles enunciated in this document are based on past experience and precedent. The purpose of these labeling guidelines is not to establish new regulatory requirements, but to provide standards so that all package inserts can be brought up to the level of the best ones written in the past.

In this proposal, the section heading "Actions" for prescription drug labeling set forth in § 3.74, which the Commissioner proposes to revoke, has been replaced by a new section entitled "Clinical Pharmacology" under proposed new § 1.112 (21 CFR 1.112). This heading more accurately describes the information required. Likewise, the "Indications" section of the labeling has been changed to "Indications and Usage," and specific instructions have been provided for describing the indications, the optimal usage of the drug, and the limitations of use. The "Adverse Reactions" section of the labeling in proposed § 1.112(c)(7) requires that pertinent information derived from experience with the class of drugs, e.g., thiazide diuretics, phenothiazines, be included as well as information on the specific drug. In addition, the Commissioner is proposing that the frequency of adverse reactions be enumerated as approximate estimates; precise percent figures will not be permitted unless there is scientific evidence from well-controlled trials substantiating such figures and when the inclusion of percent figures does not falsely imply a greater degree of accuracy than actually exists. The Food and Drug Administration will continue to require the use of prominently displayed box warnings for special problems that clearly warrant such a warning.

Information relating to possible hazards of use in pregnant women and in children has been moved from the "Warnings" section of the prescription drug labeling to the "Precautions" section. The proposed regulations on pregnancy precautions in § 1.112(c)(6) go into considerable detail, including proposed specific phraseology. This detail is believed necessary in view of past experience with confusing and inconsistent labeling relating to use in pregnancy. Pregnancy precautions are the one section in the package insert where statements on clinical usage are almost routinely based on animal data, and it is believed that such statements will be most helpful to the physician if the language is consistent in all package inserts.

Physicians need accurate information on the differences in action, mode of administration, therapeutic usefulness, and frequency and character of adverse effects among drugs used for the same indication. However, to avoid giving physicians possibly erroneous and incomplete information, the Commissioner proposes to limit such comparative statements to situations where they are based upon substantial evidence derived from adequate, and well-controlled studies designed for that specific purpose. Exceptions may be made by waiver where there is significant evidence in the scientific literature substantiating such claims.

The "Clinical Studies" and "References" sections set out in § 3.74(b) have been eliminated from the package insert in proposed new § 1.112. Except in unusual situations specifically approved by the Food and Drug Administration, this type of information is properly included in other types of labeling such as brochures. No clinical studies or references cited in such labeling may refer to indications or uses not stated in the package insert.

To assure that the reader of the labeling, package insert or other information brochure is aware of the date of the latest revision, the Commissioner is proposing a revision of § 1.106(b)(5) (21 CFR 1.106(b)(5)) to require that the date be placed prominently in the top right hand corner of the first page of such text material.

The Commissioner is also proposing that a new paragraph (b)(7) be added to § 1.106 to require that the name and place of business of the manufacturer, packer or distributor appear in the package insert or other informational brochure.

A proposal was published in the FEDERAL REGISTER of August 22, 1972 (37 FR 16877) to revise the advertising regulations pertaining to the use of comparative safety and effectiveness claims by amending § 1.106(e)(6) (ii) and (vii). The proposal stated that such claims may properly be used in advertising for a new drug or a certified antibiotic only where they have been approved by the Food and Drug Administration on the basis of data contained in an application, and that for other prescription drugs such claims must be supported by substantial evidence or substantial clinical experience. The Commissioner has given further consideration to this proposal and concludes that it should be revised and reproposed herein to state that comparative safety and effectiveness claims may properly be used in advertising for a new drug, certified antibiotic or licensed biologic only when such representations have been approved as part of the labeling in a new drug or antibiotic application or biologic license on the basis of data contained in the application. For all other prescription drugs, such claims may be made only when the claims are proved by substantial evidence derived from adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) (21 CFR 314.111(a)(5)(ii)) and are included in the labeling. Exceptions may be made by waiver when there is other scientific evidence substantiating such claims which can be accepted as adequate. This revision will make the advertising proposal consistent with the labeling proposal.

The labeling requirements proposed will eventually be applicable to the labeling of all prescription drugs, including biologics, except for any prescription drugs that are subject to the specific labeling requirements for in vitro diagnostic products in Part 328 (21 CFR 328). After the effective date of the final order on this proposed regulation, the labeling requirements would apply to all drugs as they are initially approved through the new drug application procedures or antibiotic procedures, and to biologic products as they are licensed. For prescription drugs that are currently being marketed, except for biologics and antibiotics, labeling would be revised either through old drug monographs or through procedures published pursuant to a notice in the FEDERAL REGISTER. For biologics and antibiotics, labeling would be revised upon specific notice by the Food and Drug Administration. Ample time will be allowed for effecting such changes. Recalls of old labeling will not ordinarily be required.

The package insert is a document having significant scientific, medical, legal, and administrative importance. It directly affects what may lawfully be included in advertising. Because of the significance of this proposal, the Commissioner invites comment from all persons having an interest in this subject.

In order to develop a format and standards for the content of each labeling section that are as meaningful and helpful to practitioners as possible, a draft of this proposal was circulated to pharmaceutical associations and to a wide segment of the medical community through a number of medical associations and interested individual physicians. A copy of the draft was placed on public display in the office of the Hearing Clerk, Food and Drug Administration, and notice of its availability was published in the FEDERAL REGISTER of March 7, 1974 (39 FR 8946). The draft was sent to all who requested it.

Fifty-nine comments on the draft were received from physicians, professional societies, drug manufacturers, trade associations, and individual consumers. The comments have all been reviewed and a number of the suggested changes are included in these proposed regulations. All comments are on file in the office of the Hearing Clerk, and will be reviewed again when additional comments are received on the proposal. Those comments not previously addressed or not satisfactorily addressed, as indicated by additional comments, will be answered at the time the final order is published. The major issues addressed in the comments, other than those dealing with scientific and medical problems, were of a legal nature. The Commissioner has concluded that it is advisable to address the following such comments at this time:

1. Several comments raised the question of the legal status of the package insert and the precise role that the insert is intended to play in the practice of medicine. The comments contended that court decisions have shown that use of a drug for an indication not in the package insert may expose the physician to some form of legal jeopardy. The comments stated that to maintain the Food and Drug Administration's credibility in its professed concern with the legal impact of the package insert on the practice of medicine, the Food and Drug Administration must recognize that this is the case and act to protect physicians and

their patients in this area. The comments recommended that the proposed regulations be revised to require an appropriate statement in package inserts that, in addition to the conditions of use which the manufacturer may recommend to physicians in compliance with the law and Food and Drug Administration regulations, there are other conditions of use for which the drug may be regarded as safe and effective on the basis of the experience of critical physicians using the drug in the practice of medicine over a period of years.

The Commissioner stated in a separate notice of proposed rule making published in the FEDERAL REGISTER of August 15, 1972 (37 FR 16503), concerning the use of a drug for conditions not included in its labeling, that the labeling is not intended either to preclude the physician's use of his best judgment in the interest of the patient or to impose liability if he does not follow the package insert. The Commissioner clearly recognizes that the labeling of a marketed drug does not always contain all the most current information available to physicians relating to the proper use of the drug in good medical practice. Advances in medical knowledge and practice inevitably precede labeling revision by the manufacturer and formal labeling approval by the Food and Drug Administration. Good medical practice and patient interests thus require that physicians be free to use drugs according to their best knowledge and judgment. Certainly, where a physician uses a drug for a use not in the approved labeling, he has the responsibility to be well informed about the drug and to base such use on a firm scientific rationale or on sound medical evidence, and to maintain adequate medical records of the drug's use and effects, but such usage in the practice of medicine is not in violation of the Federal Food, Drug, and Cosmetic Act. This position will be restated in the final order on the August 15, 1972 proposal which will be published in the near future. The liability of a physician in his use of a drug depends upon all of the facts surrounding that use, and not upon whether or not the indication is in the package insert.

The Commissioner concludes, however, that it is neither lawful nor in the interest of good patient care for the package insert to contain references to indications or usages for which substantial evidence of safety and effectiveness is not available. Physicians clearly have access to new information on drugs through the medical literature, scientific meetings, postgraduate courses, and professional contacts with colleagues. The package insert is not intended under the law to serve as a totally current repository of all such information. It is intended instead to be an authoritative document which contains only those indications and usages based upon substantial evidence of safety and effectiveness. Before a new indication can be included in the package insert, the law requires that substantial evidence based on adequate and well-controlled clinical trials supporting the safety and effectiveness of the new indication be developed by the manufacturer and be submitted to, and approved by, the Food and Drug Administration. Until the standard of substantial evidence is met, there is no legal basis for including in the package insert any suggestion of other uses for which the drug may be regarded as safe and effective.

2. One comment raised the question of what effect the proposed regulations would have on the Drug Efficacy Study Implementation program which permits possibly effective and probably effective indications to be used pending submission of additional evidence of effectiveness and further action. The proposed labeling regulations make no provision for the continued use of any indications for use rated as less than "effective".

The Commissioner advises that the requirement in § 3.81 (21 CFR 3.81) that labeling of drugs reviewed in the Drug Efficacy Study and containing indications with less-than-effective ratings include an appropriate qualification is not affected by this proposed regulation. The qualifying statements will continue to be required until the indication either has been removed or has been approved on the basis of data submitted to the Food and Drug Administration. These regulations are not incompatible.

3. Several comments objected to the statement in the "Adverse Reactions" section of the prescription drug labeling in proposed § 1.112(c)(7)(i) which requires the listing of adverse reactions that occur with the subject drug and with drugs of the same chemical or pharmacological class, if applicable. The comments described this as an objectionable attempt to require class labeling.

The Commisioner concludes that it is essential to the safe use of a drug for the physician to know all adverse effects that are likely to occur with a drug. Where drugs are closely related chemically or parmacologically, the inclusion of all adverse reaction information, whether or not all such reactions have been reported with the specific drug, is medically sound. There are many times when the labeling of such drugs should be essentially identical and may be called class labeling. Without this provision, new drugs in a class may enter the market with the appearance of increased safety over already marketed products merely because of insufficient marketing experience with the new drug. Class labeling is currently in effect for a number of drugs and will become more commonplace in the future.

4. Several objections were received on proposed § 1.112(c)(6)(ii), which provides for patient brochures or printed instructions for the patient. The comments contended that section 503(b)(2) of the act (21 U.S.C. 353(b)(2)) exempts a drug dispensed by filling or refilling a prescription of a practitioner from certain labeling requirements under stated conditions, including the condition, as stated in the act, that "* * * the drug bears a label containing * * * and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. * * *" and if these conditions, among others, are met, the drug as dispensed on prescription is exempt from the requirements of the act that its labeling bear adequate directions for use and adequate warnings. The comments question the authority of the Food and Drug Administration to establish labeling requirements from which a drug is exempt by the act.

The Commissioner disagrees with this contention. Section 505 of the act (21 U.S.C. 355) provides that a new drug application (NDA) may be approved only if it is shown to be safe and effective in use under the conditions set out in its labeling, and section 201(p) (21 U.S.C. 321(p)) similarly provides an exemption from the requirement of an NDA only if the drug is generally recognized as safe and effective under the conditions of use set out in its labeling. Moreover, both sections 502(a) (21 U.S.C. 352(a)) and 505(d) prohibit prescription drug labeling that is false or misleading in any particular, and section 201(n) explicitly provides that the failure to reveal material facts can be misleading. Accordingly, the act requires the Commissioner to make a determination that the information contained in the labeling for a prescription drug is sufficient to assure the safe and effective use of that drug by consumers. The Commissioner concludes that such a determination may well require specific information to be provided to consumers about the drug, as has already been required for the oral contraceptives in § 310.501 (21 CFR 310.501).

The primary purpose of the provision in section 503(b)(2) of the act exempting a prescription drug from adequate directions for use and warnings was to avoid self-diagnosis and self-administration of drugs that require professional supervision for safe use. The requirement of printed patient information does not contradict this purpose. The purpose of such information is to ensure safe and effective use of a prescription drug by consumers after it has been prescribed by the physician. Nothing in the legislative history of section 503(b) or in the act itself suggests that Congress intended to preclude a requirement of labeling directed to the patient to promote safe and effective use of the drug.

5. A comment questioned the legal authority for withdrawing approval of drugs that are safe, effective, and not misbranded for failure to comply with the various ambiguous requirements embodied in the proposal.

The Commissioner anticipates that the need to withdraw approval of new drug applications for failure to comply with the labeling requirements will not often occur, and will in any event be undertaken only in compliance with the statute. As revised labeling is submitted to the Food and Drug Administration for review, where deficiencies are encountered they will be brought to the attention of applicants, and the labeling will not be approved until all problems are resolved. Only where the labeling under which a drug is marketed continues to violate section 505(e) of the act will withdrawal of approval be instituted.

6. Several comments objected to the proposed revisions of § 1.105 (21 CFR 1.105), contending that it proposes to establish "on the basis of a waiver" a requirement for prior approval of the content of an advertisement. The comments state that this requirement appears to be directly contrary to the provision in section 502(n) of the act that, except in extraordinary circumstances, prior approval by the Secretary of the content of any advertisement shall not be required.

The Commissioner advises that the purpose of this proposal is to set forth definitively to the industry the requirements for making comparative safety or effectiveness claims in drug advertisements. The purpose of the waiver of the requirement for drugs for which new drug or antibiotic application approvals are not required is to provide a procedure for the rare circumstances in which it may be appropriate to permit a comparative claim without substantial evidence of effectiveness. These exceptions cannot be addressed broadly and must be reviewed on an individual basis. This does not establish a procedure for preclearance of the content of an advertisement, but rather a mechanism for determining whether information is available to support a comparative claim. The alternative to this approach would be to prohibit all comparative claims where there is a lack of substantial evidence of effectiveness.

7. Objection was raised to the proposed revisions of § 1.105 on the grounds that "substantial evidence" applies only to new drugs and antibiotics and that the provisions of the act conferring jurisdiction over prescription drug advertisements does not include any requirement for "substantial evidence."

The Commissioner notes that the Supreme Court in the recent decisions in "Weinberger v. Hynson, Westcott and Dunning, Inc.," 412 U.S. 609 (1973) and "Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973), made it clear that the requirement of substantial evidence applies to the definition of a "new drug" in section 201(p) of the act. Thus, a drug is generally recognized as safe and effective only if there is a body of evidence equivalent to that required for approval of new drugs and antibiotics, supporting all claims made for that drug in labeling and advertising. Accordingly, all effectiveness claims for any drug are subject to the substantial evidence standard.

8. Several objections were raised to the provision in the "How Supplied" section in the draft proposal that would permit the optional listing of other dosage forms and potencies of the drug available on the market. The basis for the objections were that this practice could be misleading to the prescriber in that it would imply equivalency to other firms' products when such was not necessarily the case. It was also contended that the practice could be confusing to the prescriber in regard to how the product was supplied by the firm whose package insert contains the information.

The Commissioner agrees that this section could cause confusion and has therefore deleted the provision from § 1.112(c)(10) that would allow the optional listing of other commercially available dosage forms.

9. Objections were raised to the proposed inclusion of the requirement for the new labeling format in § 1.106(b)(4) which pertains to all labeling including promotional labeling, rather than in § 1.106(b)(3) which pertains only to labeling on or within the package, on the grounds that, if all promotional labeling had to comply with proposed new § 1.112, the net effect would be a requirement for premarketing clearance of the form and content of all labeling.

The Commissioner rejects this comment. Proposed § 1.112 properly applies to all labeling (except reminder-piece labeling) and therefore should be referenced in § 1.106(b)(4). This does not alter existing Food and Drug Administration policy in this area. The application of the requirements of the proposed § 1.112 to all labeling (except reminder-piece labeling) does not in any way impose a new requirement for premarketing clearance of the form or content of labeling. The current regulations do not require preclearance of all labeling if the parts of the labeling furnishing directions, warnings, and information for use of the drug are the same in language and emphasis as labeling approved or permitted, and if any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

These regulations shall be effective 6 months after the date of the final order, except that § 1.106(b)(5) and (7) shall not be effective until printing plates are revised in the normal course of business or until 12 months after the date of the final order, whichever occurs first. After the effective date of the final regulations, all new or pending applications for new drugs or antibiotics and license applications for biologics shall be in the format and shall contain the information specified in § 1.112. For prescription drugs that are being marketed, except for biologics and drugs subject to section 507 of the Federal Food, Drug, and Cosmetic Act, the labeling shall be revised in accordance with § 1.112 at the time old drug monographs are promulgated or upon specific notification by the Food and Drug Administration published in the FEDERAL REGISTER. For prescription drugs which are biologics or subject to section 507 of the Federal Food, Drug, and Cosmetic Act, the labeling shall be revised upon specific notice by the Food and Drug Administration published in the FEDERAL REGISTER. Ample time will be allowed for effecting such changes. Recalls of old labeling will not ordinarily be required.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 503, 505, 506, 507, 701, 52 Stat. 1050–53, 1055–1056, as amended, 55 Stat. 851, 59 Stat. 463, as amended; 21 U.S.C. 352, 353, 355, 356, 357, 371) and to the provisions of the Public Health Service Act (sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262), and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes that Parts 1 and 3 be amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

By amending § 1.105 by adding a new sentence to paragraph (e)(6)(ii) and (vii); as revised § 1.105 (e)(6)(ii) and (vii) reads as follows:

§ 1.105 Prescription drug advertisements.

* * * * * * *

(e) * * *

(6) * * *

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience. Advertising for a prescription drug may not either directly or by implication, e.g., by use of comparative test data or reference to published reports, represent that the drug is safer or more effective than another drug or contain a quantitative statement of safety or effectiveness (*a*) unless the representation has been approved as part of the labeling in a new drug or antibiotic application or biologic licence, or (*b*) if the drug is not a new drug or certified or released antibiotic, or biologic, unless the representation of safety or effectiveness is proved by substantial evidence derived from adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation.

* * * * *

(vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated. Data which demonstrate activity or effectiveness for a prescription drug in animal or in vitro tests and which have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be used in advertising only under the following circumstances: In vitro data for antiinfective drugs may be included in the brief summary or full disclosure portion of the advertisement, but not in the promotional portion of the advertisement, if such data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown." For other classes of drugs, in vitro and animal data which have not been shown by adequate and well-controlled clinical studies as defined

in § 314.111(a)(5)(ii) of this chapter to be pertinent to clinical use may be used in the brief summary or full disclosure portion of the advertisement, but not in the promotional portion of the advertisement, only on the basis of a waiver after a showing that such requirements are not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation.

2. By amending § 1.106 by adding a new paragraph (b)(4)(iii), by revising paragraph (b)(5), and by adding a new paragraph (b)(7) as follows:

§ 1.106 Drugs and devices, directions for use.

* * * * *

(b) * * *

(4) * * *

(iii) The information required, and in the format specified by § 1.112 or, where applicable, § 328.10 of this chapter.

(5) All labeling, except labels and cartons (unless such labeling contains information required by paragraph (b)(3)(i) of this section in lieu of a package insert) bearing adequate information for use of the drug also bears the date of the issuance or date of the latest revision of such labeling prominently placed in the top right hand corner of the first page of the text of such labeling.

(6) [Reserved]

(7) All labeling described in paragraph (b)(4) of this section bears conspicuously the name and place of business of the manufacturer, packer, or distributor.

3. By adding a new § 1.112 to read as follows:

§ 1.112 Labeling for prescription drugs used in man.

(a) Prescription drug labeling furnishing adequate information for the safe and effective use of a drug as required under § 1.106(b)(4), except for products subject to Part 328 of this chapter, shall contain the information required, shall be in the format specified, and shall meet the following general criteria:

(1) Labeling shall contain the essential scientific information needed for safe and effective use of the drug.

(2) Labeling shall be informative and accurate and not be promotional in tone or false or misleading in any particular.

(3) Labeling shall be based whenever possible on data derived from human experience. There may be no implied claims or suggestions of drug use where there is inadequate evidence of safety and effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling, headings for which are listed in paragraph (b) of this section.

(b) Labeling shall ordinarily contain information in the format and order and with the section headings as follows:

Description
Clinical Pharmacology
Indications and Usage
Contraindications
Warnings
Precautions
Adverse Reactions
Overdosage
Dosage and Administration
How Supplied

The following section heading may be used where appropriate:

Animal Pharmacology and/or Animal Toxicology

Any section or subsection of the labeling may be omitted if clearly nonapplicable.

(c) The specific information appearing under each section heading listed in paragraph (b) of this section shall be as follows:

(1) *Description.* (i) Under this section heading, the labeling shall contain:

(*a*) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug product;

(*b*) The type of dosage form and the route of administration to which the labeling applies;

(*c*) The same qualitative and/or quantitative ingredient information as required for labels;

(*d*) If the product is sterile, a statement of that fact;

(*e*) The pharmacological or therapeutic class of the drug product;

(*f*) The chemical name and structural formula.

(ii) When appropriate, other important chemical or physical information, such as physical constants, pH, etc., should also be included.

(2) *Clinical pharmacology.* (i) Under this section heading, the labeling shall contain a concise factual summary of the clinical pharmacology and actions of the drug in man. The summary may include information based on in vitro and/or animal data when such information is essential in describing the biochemical and/or physiological mode of action of the drug or is otherwise pertinent to human therapeutics. Pharmacokinetic information which is important to safe and effective use of the drug shall be included, if known, e.g., degree and rate of absorption, pathways of biotransformation, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, and degree of uptake by a particular organ. Inclusion of pharmacokinetic information shall be restricted to that which relates to clinical use of the drug. If the pharmacological mode of action of the drug is unknown or if important metabolic or pharmacokinetic data in man are unavailable, this shall be stated.

(ii) Data which demonstrate activity or effectiveness in in vitro or animal tests and which have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section of the labeling only under the following circumstances. In vitro data for anti-infective drugs may be included if such data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown." For other classes of drugs, in vitro and animal data which have not been shown by adequate and well-controlled clinical studies, as defined in § 314.111(a)(5)(ii) of this chapter, to be pertinent to clinical use may be used only on the basis of a waiver after a showing that such requirements are not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation.

(3) *Indications and usage.* (i) Under this section heading, the labeling shall state explicitly:

(*a*) That the drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, e.g., penicillin is indicated for the treatment of pneumococcal pneumonia; or

(*b*) That the drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, e.g., chlorothiazide is indicated for the treatment of edema in patients with congestive heart failure; or

(*c*) That the drug is indicated for the relief of symptoms associated with a disease or syndrome, e.g., chlorpheniramine is indicated for the symptomatic relief of nasal congestion in patients with vasomotor rhinitis. If the drug is used for a particular indication only in conjunction with a primary mode of therapy, e.g., diet, surgery, or some other drug, the drug shall be labeled as an adjunct to such mode of therapy. All such indications shall be supported by substantial evidence based on adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) of this chapter.

(ii) The following additional information shall also be included under this section of the labeling:

(*a*) The limitations of usefulness of the drug. Where evidence is available to support the safety and effectiveness of the drug only in selected subgroups of the larger population with a disease, syndrome, or symptom under consideration, e.g., patients with mild disease or patients in a special age group, this shall be stated. Any specific tests needed for selection or monitoring of the patients who need the drug shall be stated, e.g., microbe susceptibility tests. Information on the approximate kind, degree, and duration of improvement to be anticipated shall be given when available and shall be based on adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) of this chapter unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation.

(*b*) If safety considerations are such that the drug should be reserved for certain situations, this information shall be included, e.g., cases refractory to other drugs.

(*c*) If there are specific conditions which should be met before the drug is used on a long term basis, e.g., demonstration of responsiveness to the drug in a short term trial, these conditions shall

be stated; or if the indications for long term use are different from those of short term use, the specific indications for each use shall be stated.

(d) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for that condition, but the preponderance of evidence related to such use indicates that the drug is ineffective, the package insert shall state that there is a lack of evidence that the drug is effective for that use.

(e) Any statements comparing the safety or effectiveness, either greater or lesser, of the drug with other agents for the same indication shall be supported by substantial evidence derived from adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) of this chapter unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation.

(4) *Contraindications.* Under this section heading, the labeling shall state those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. Such situations include: Administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities shall be listed, e.g., if hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication. If no contraindications are known, this section of the labeling shall state: "None."

(5) *Warnings.* Under this section heading, the labeling shall state serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps which should be taken if they occur. A warning shall be included in labeling as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling may be required if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those which may lead to death or serious injury, may be required to be placed in a prominently displayed box. Such box warnings shall ordinarily be based on clinical data and not animal experiments. When box warnings are required, their location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if pertinent, the approximate mortality and morbidity rates for patients sustaining the reaction shall be expressed as provided under the "Adverse Reactions" section of the labeling.

(6) *Precautions.* Under this section heading, the labeling shall contain the following subsections as appropriate for the drug product:

(i) General: Under this subsection of the labeling shall be listed any special care to be exercised by the practitioner for safe and effective use of the drug, e.g., precautions concerning drug abuse or use of other drugs that may be harmfully additive.

(ii) Information for the patient: Under this subsection of the labeling, information to be given to patients for safe and effective use of the drug shall be included, e.g., precautions concerning driving or use of drugs that may be harmfully additive. Any printed patient information shall be referenced under the "Precautions" section of the labeling and, when appropriate, reprinted at the end of the package insert.

(iii) Essential laboratory tests: Under this subsection of the labeling shall be listed laboratory tests which are needed to follow the patient's response or to identify possible adverse reactions.

(iv) Clinically significant drug interactions: This subsection of the labeling shall provide specific practical guidance to the physician on avoiding and/or handling clinically significant drug interactions which may occur in vivo in patients taking the drug. Specific other drugs or classes of drugs with which the drug under consideration may interact in vivo shall be listed, and the mechanism(s) of the interaction briefly described. Information in this subsection of the labeling shall be limited to that pertinent to clinical use of the drug in patients. Drug interactions supported only by animal or in vitro experiments should not be included. Drug incompatibilities, i.e., drug interactions which may occur when drugs are mixed in vitro, as in a solution for intravenous administration, shall be discussed under "Dosage and Administration" rather than under this subsection of the labeling.

(v) Carcinogenesis, mutagenesis, impairment of fertility: The labeling shall state whether long term studies in animals have been performed to evaluate carcinogenic potential and, if so, state the species and results. When reproduction studies or other data in animals reveal a problem or potential problem concerning mutagenesis or impairment of fertility, in either males or females, this information shall be included. Any precautionary statement on these topics should include practical, relevant advice to the physician on the significance of these animal findings, which usually will be to the effect that use of the drug should be limited to patients in whom the benefits clearly exceed the potential hazards. If there is evidence from human data that the drug may be carcinogenic or mutagenic or that it impairs fertility, this information shall be included under the "Warnings" section of the labeling. Also, under "Precautions," the labeling shall state: "See 'Warnings' section for information on carcinogenesis, mutagenesis and impairment of fertility."

(vi) Pregnancy: For drugs not absorbed systemically, this subsection of the labeling shall be omitted. For all other drugs, this subsection of the labeling shall state whether the drug is in category A, B, C, D, E, or X, followed by the required statement delineating the types of studies done or not done and the data derived from such studies as follows:

(a) Pregnancy category A. When adequate reproduction studies in animals have been performed and well-controlled trials relating to fetal risk in the human are available, and both animal and human data are negative for fetal abnormalities, the labeling shall state: "Pregnancy category A. Reproduction studies have been performed in (*kind of animals*) and have revealed no evidence of impaired fertility or harm to the fetus due to (*name of drug*). In addition, studies in pregnant women (describe the studies briefly if desired) have shown that (*name of drug*) does not increase the risk of fetal abnormalities when administered during the (*first, second, and/or third (or all) trimester(s)*) of pregnancy. (*Name of drug*) is without established risk to the fetus in the (*first, second, and/or third (or all) trimester(s)*) of pregnancy when used in the recommended dosage."

(b) Pregnancy category B. When adequate reproduction studies in animals are negative for fetal abnormalities and well-controlled trials relating to fetal risk in the human are not available, but investigational or marketing experience has not produced any positive evidence of adverse effects on the fetus (a common situation for post-1962 prescription drugs), the labeling shall state: "Pregnancy category B. Reproduction studies have been performed in (*kind of animals*) and have revealed no evidence of impaired fertility or harm to the fetus due to (*name of drug*). There are no well-controlled studies in pregnant women, but (*investigational or marketing*) experience does not include any positive evidence of adverse effects on the fetus. Although there is no clearly defined risk, such experience cannot exclude the possibility of infrequent or subtle damage to the fetus. (*Name of drug*) should be used in pregnant women only when clearly needed."

(c) Pregnancy category C. When neither adequate reproduction studies in animals nor well-controlled trials relating to fetal risk in humans are available, but investigational or marketing experience has not produced any positive evidence of adverse effects on the fetus (a common situation for pre-1962 prescription drugs), the labeling shall state: "Pregnancy category C. Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. There are no well-controlled studies in pregnant women, but (*investigational or marketing*) experience does not include any positive evidence of adverse effects on the fetus. Although there is no clearly

defined risk, such experience cannot exclude the possibility of infrequent or subtle damage to the human fetus. (*Name of drug*) should be used in pregnant women only when clearly needed."

(*d*) Pregnancy category D. When adequate reproduction studies in animals have demonstrated fetal abnormalities but there is no positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, and the benefit-risk considerations are such that use of the drug may be necessary in pregnant women, the labeling shall state: "Pregnancy category D. (*Name of drug*) has been shown to be teratogenic in (*name(s) of species*) when given in doses (*number*) times the highest dose recommended for human use. (Describe the animal data as appropriate). There are no well-controlled studies in pregnant women, but (*investigational or marketing*) experience does not include any positive evidence of adverse effects on the fetus. Since such experience cannot exclude possibility of fetal damage, (*name of drug*) should be used during pregnancy only if the benefit clearly justifies the potential risk to the fetus."

(*e*) Pregnancy category E. When there is positive evidence of fetal risk based on adverse reaction data from investigational or marketing experience or well-controlled studies in humans, but the benefit-risk considerations are such that use of the drug may be necessary in pregnant women, i.e., when the drug is needed in a life-threatening situation or serious disease where safer drugs cannot be utilized or are ineffective, under "Precautions", the labeling shall state: "Pregnancy category E. See 'Warnings' section." Under "Warnings", the labeling shall state: "(*Name of drug*) can cause fetal damage when administered to pregnant women. (Describe the human data and pertinent animal data.) If this drug must be used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risks to the fetus, and the possibility of termination of the pregnancy should be discussed in light of those risks."

(*f*) Pregnancy category X. When animals or well-controlled studies in humans have demonstrated fetal abnormalities and/or there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, and the benefit-risk considerations are such that use of the drugs will never be necessary in pregnant women, i.e., when safer drugs or other forms of therapy are available, under "Precautions", the labeling shall state: "Pregnancy category X. See 'Contraindications' section." Under "Contraindications", the labeling shall state: "(*Name of drug*) can cause fetal damage when administered to pregnant women. (Describe the human data and pertinent animal data). (*Name of drug*) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risks to the fetus, and the possibility of termination of the pregnancy should be discussed in the light of those risks."

(*g*) Any situation concerned with use of the drug in pregnancy which is not covered by one of the previous pregnancy categories shall be considered on an ad hoc basis by the sponsor and the Food and Drug Administration.

(vii) Labor and delivery: If the drug has a recognized use during labor or delivery, this subsection of the labeling shall contain information on the effect of this drug on the fetus, on the duration of labor, and on the possibility that forceps delivery or other intervention will be necessary. If no such data are available, this subsection of the labeling shall state, as appropriate: "It is not known whether use of this drug during labor or delivery has immediate or delayed adverse effects on the fetus, or whether it prolongs the duration of labor or increases the possibility of forceps delivery or other obstetrical intervention."

(viii) Nursing mothers: For drugs absorbed systemically, information with respect to excretion of the drug in human milk and effects on the nursing infant shall be described, when known. If there are no data, this shall be indicated with the following statement: "It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk." If an adverse effect has been noted in animal offspring, this shall be described.

(ix) Pediatric use: Specific pediatric indications, if any, shall be described under the "Indications and Usage" section of the labeling, and appropriate pediatric dosage shall be stated under the "Dosage and Administration" section of the labeling. Pediatric usage for indications approved for adults shall be based on adequate and well-controlled studies as defined in § 314.111(a) (5) (ii) of this chapter unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation. If this requirement cannot be met, the following statement shall be included under this subsection of the labeling: "Safety and effectiveness in children below the age of (__) have not been established." If use of the drug in premature or neonatal infants, or in older children, is associated with a specific hazard, this shall be described in this subsection of the labeling; or, if appropriate, the hazard shall be included in the "Contraindications" or "Warnings" section of the labeling and reference to it made in this subsection of the labeling.

(7) *Adverse reactions.* An adverse reaction is an undesirable effect reasonably associated with the use of the drug, which may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence.

(i) This section of the labeling shall include a listing of the adverse reactions which occur with the subject drug and with drugs of the same chemical or pharmacologic class, if applicable. Specific information on the severity and mechanism of the important adverse reactions associated with the drug, as well as information on the clinical management of such reactions, shall be included.

(ii) In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, as appropriate. The approximate frequency of each adverse reaction shall be expressed in rough estimates or orders of magnitude essentially as follows: "The most frequent adverse reaction(s) to (*name of drug*) is (are) (*list reactions*). This (These) occur(s) in about (e.g., one-third of patients; one in 30 patients; less than one-tenth of patients). Less frequent adverse reactions are (*list reactions*) which occur in approximately (e.g., one in 100 patients). Other adverse reactions, which occur rarely, in approximately (e.g., one in 1,000 patients), are (*list reactions*)." Percent figures will not ordinarily be permissible; exception to this may be made when percent figures are documented by adequate and well-controlled studies as defined in § 314.111 (a) (5) (ii) of this chapter and upon a showing that such figures appropriately reflect general experience and do not falsely imply a greater degree of accuracy than actually exists.

(iii) Any potentially fatal adverse reaction shall be placed under the "Warnings" section of the labeling or, if appropriate, the "Contraindications" section of the labeling.

(iv) Any claim comparing the subject drug with other drugs in terms of frequency, severity, or character of adverse reactions shall be based on substantial evidence derived from adequate and well-controlled studies as defined in § 314.111 (a) (5) (ii) of this chapter unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation constitutes adequate scientific substantiation.

(8) *Overdosage.* This section of the labeling shall describe the signs, symptoms, and laboratory findings of overdosage and the general principles of treatment. It shall include specific information, if available, on emergency treatment, antidotes, and the value of therapeutic measures such as forced emesis or diuresis or dialysis.

(9) *Dosage and administration.* This section of the labeling shall state the recommended usual dose, the usual dosage range, and, where appropriate, an upper limit beyond which the drug should not be prescribed; dosages shall be stated for each indication when appropriate. It shall include the intervals recommended

between doses, the optimal method of titrating dosage, the usual duration of treatment, and any modification of dosage needed in special patient populations, e.g., in children, in geriatric age groups, or in patients with renal or hepatic disease. Specific tables or nomographs may be included to clarify dosage schedules. This section shall also contain specific direction on dilution, preparation, and administration of the dosage form, if needed; storage conditions for stability of the drug or reconstituted drug, where important; and essential information on drug incompatibilities if the drug is mixed in vitro with other drugs.

(10) *How supplied.* This section of the labeling shall include information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. Such information shall ordinarily include:

(i) The potency of the dosage form, e.g., 10 mg. tablets, in metric system and, if the apothecary system is used, it shall be placed in parentheses after the metric designation;

(ii) The units of issue of the dosage form, e.g., bottles of 100;

(iii) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, National Drug Code, etc.; and

(iv) Special handling and storage conditions.

(11) *Animal pharmacology and/or animal toxicology.* In most cases, the labeling will not include this section. Significant animal data necessary for safe and effective use of the drug in humans shall ordinarily be included in one or more of the sections of the labeling described above, as appropriate. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this one may be used.

(d) The date of issuance or the date of the latest revision as required by § 1.106 (b) (5) shall be placed prominently in the top right hand corner of the first page of the text of such labeling.

(e) "Clinical Studies" and "References" sections shall not be used in the labeling unless by waiver or unless the citation is in lieu of a detailed description of a subject that is of limited interest but nonetheless important, as for example, a complex assay procedure. Reference to a specific important clinical study(s) may be made in the text of the package insert when this is essential to an understandable presentation of the available information. Such references shall be used in rare circumstances only. No clinical studies or references cited in labeling may refer to indications or uses not stated in the "Indications" section.

(f) A waiver of the requirements of § 314.111(a) (5) (ii) of this chapter pursuant to this section or § 1.105(e) (6) (ii) and (vii) shall be requested by submitting pertinent data, information and rationale in writing, in triplicate, to the Director, Bureau of Drugs, Food and Drug Administration or, where applicable, the Director, Bureau of Biologics, Food and Drug Administration. Such waiver shall be granted or denied in writing by such Director or his designee.

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

§ 3.74 [Revoked]

4. In Part 3 by revoking § 3.74.

Interested persons may, on or before June 6, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: March 18, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-8754 Filed 4-4-75;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 71]

[Airspace Docket No. 75-GL-12]

CONTROL ZONE AND TRANSITION AREA

Proposed Alteration

The Federal Aviation Administration is considering amending Part 71 of the Federal Aviation Regulations so as to alter the control zone and transition area at Marion, Indiana.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Director, Great Lakes Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018. All communications received on or before May 7, 1975 will be considered before action is taken on the proposed amendments. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Regional Air Traffic Division Chief. Any data, views or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become a part of the record for consideration. The proposals contained in this notice may be changed in the light of comments received.

A public docket will be available for examination by interested persons in the Office of the Regional Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

The controlled airspace at Marion, Indiana, has been reviewed and was found to need revision to protect the present approach procedures.

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations as hereinafter set forth:

§ 71.171 [Amended]

1. In § 71.171 (40 FR 354), the following control zone is amended to read:

MARION, INDIANA

Within a 5-mile radius of the Marion Municipal Airport, (Latitude 40°29'27" N., Longitude 85°40'43" W.); and within 2.5 miles each side of the Marion VOR 042°, 211° and 320° radials; extending from the 5-mile radius to 6 miles northeast and northwest and 5.5 miles southwest of the VOR. This control zone is effective during the specific dates and times established in advance by a Notice to Airman. The effective date and time will thereafter be continuously published in the Airmen's Information Manual.

§ 71.181 [Amended]

2. In § 71.181 (40 FR 441), the following transition area is amended to read:

MARION, INDIANA

That airspace extending upward from 700 feet above the surface within a 5-mile radius of the Marion Municipal Airport, Marion, Indiana (Latitude 40°29'27" N., Longitude 85°40'43" W.); and within 3 miles each side of the Marion VOR 042°, 211° and 320° radials, extending from the 5-mile radius to 8 miles northeast, southwest and northwest of the VOR.

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

Issued in Des Plaines, Illinois, on March 10, 1975.

JOHN M. CYROCKI,
Director, Great Lakes Region.

[FR Doc.75-8352 Filed 4-4-75;8:45 am]

[14 CFR Part 71]

[Airspace Docket No. 75-EA-17]

TRANSITION AREA

Proposed Alteration

The Federal Aviation Administration is considering amending § 71.181 of Part 71 of the Federal Aviation Regulations so as to alter the Martinsburg, W. Va., Transition Area (40 FR 536).

A review of the airspace requirements for the Martinsburg, W. Va., terminal area indicates that alteration of the transition area is required to reflect the current transition area requirements for IFR arrivals and departures at Martinsburg Municipal Airport.

Interested parties may submit such written data or views as they may desire. Communications should be submitted in triplicate to the Director, Eastern Region, Attn: Chief, Air Traffic Division, Department of Transportation, Federal Aviation Administration, Federal Building, John F. Kennedy International Airport, Jamaica, New York 11430. All communications received on or before May 7, 1975 will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements may be made for informal conferences with Federal Aviation Administration officials by contacting the Chief, Airspace and Procedures Branch, Eastern Region.