of the funds, property, and claims vested in the Board of the trustees pursuant to this section.

(c) Any person to whom funds, property, or claims have been transferred or delivered pursuant to this section shall be subject to the same obligation imposed upon the Board and upon the trustee.

(d) A reasonable effort shall be made by the Board or its trustees to return to producers any residual funds not required to defray the necessary expenses of liquidation. If it is found impractical to return such remaining funds to producers, such funds shall be disposed of in such manner as the Secretary may determine to be appropriate.

§ 1207.364 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this plan or of any regulation issued pursuant thereto, or the issuance of any amendment to either thereof, shall not (a) affect or waive any right, duty, obligation, or liability which shall have arisen or which may thereafter arise in connection with any provision of this plan or any regulation issued thereunder, or (b) release or extinguish any violation of this plan or any regulation issued thereunder, or (c) affect or impair any rights or remedies of the United States, or of the Secretary, or of any other person, with respect to any such violation.

§ 1207.365 Personal liability.

No member of the Board shall be held personally responsible, either individually or jointly with others, in any way whatsoever to any person for errors in judgments, mistakes, or other acts, either of commission or omission, as such member except for acts of willful misconduct, gross negligence, or those which are criminal in nature.

§ 1207.366 Separability.

If any provision of this plan is declared invalid or the applicability thereof to any person or circumstance is held invalid, the validity of the remainder of this plan or applicability thereof to other persons or circumstances shall not be affected thereby.

[FR Doc.72-105 Filed 1-4-72;8:47 am]

[9 CFR Part 327]

IMPORTATION OF MEAT AND MEAT PRODUCTS

Proposed Addition of El Salvador to List of Approved Countries

Notice is hereby given in accordance with the administrative procedure provisions in 5 U.S.C. 553, that, pursuant to the authority contained in the Federal Meat Inspection Act (34 Stat. 2160, as amended, 21 U.S.C. 601 et seq.), the Consumer and Marketing Service is considering amending § 327.2(b) of the Federal meat inspection regulations (9 CFR Part 327) by adding El Salvador to the list of countries specified therein.

Statement of considerations. The Federal Meat Inspection Act prohibits the importation into the United States of carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines, capable of use as human food, unless they comply with all the provisions of the Act and regulations issued thereunder applicable to such articles in commerce within the United States. Such articles from approved plants in the countries listed in § 327.2 (b) are eligible for importation into the United States as provided in the regulations. The laws and regulations of El Salvador concerning these matters have been reviewed and appear to be acceptable. Further, on-site reviews of the export meat inspection program of El Salvador indicate that it is equal to our program in the United States. Certificates issued by the El Salvador officials for export of carcasses, parts thereof, meat and meat food products to the United States are reliable.

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 30 days after the date of publication of this notice in the FEDERAL REGISTER.

Persons desiring opportunity for oral presentation of views should address such requests to the Director, Field Operations Division, Consumer and Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, so that arrangements may be made for presentation of such views within the 30-day period. A transcript will be made of all views orally presented.

All written submissions and transcripts of oral views made pursuant to this notice will be made available for public inspection unless the person making the submission requests that it be held confidential and a determination is made that a proper showing in support of the request has been made on the grounds that its disclosure could adversely affect such person by disclosing information in the nature of trade secrets or commercial or financial information obtained from any person and privileged or confidential. If it is determined that a proper showing has been made in support of the request, the material will be held confidential; otherwise, notice will be given of denial of such a request and an opportunity afforded for withdrawal of the submission. Requests for confidential treatment will be held confidential (7 CFR 1.27(c)).

Comments on the proposal should bear a reference to the date and page number of this issue of the FEDERAL REGISTER.

Done at Washington, D.C., on December 29, 1971.

G. R. GRANGE,
Acting Administrator.

[FR Doc.72-104 Filed 1-4-72;8:46 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 130]

OVER-THE-COUNTER DRUGS

Proposal Establishing Rule Making Procedures for Classification

Because self-medication is essential to the Nation's health care system, it is imperative that over-the-counter (OTC) drugs available for human use be safe and effective and bear fully informative labeling. The Food and Drug Administration is concerned that some formulations presently on the market do not have their claimed effect and/or do not bear adequate labeling for safe and effective use by the laity.

Prior to the enactment in 1938 of the Federal Food, Drug, and Cosmetic Act, all drugs were marketed without first undergoing review by the Food and Drug Administration. Under the 1938 act, the Food and Drug Administration was given authority to review, prior to marketing, the safety data on those drugs not generally recognized as safe under their intended uses. Under the Drug Amendments of 1962, which amended the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration was given authority to review, prior to marketing, the safety and effectiveness of those drugs not generally recognized as safe and effective for their intended use. Pursuant to the 1962 amendments, the Food and Drug Administration was also required to review the efficacy claims of those new drugs introduced into the market between 1938 and 1962. Because of the greater potential for harm of prescription drugs, the review of such drugs was conducted as a matter of first priority and is nearing completion. It is now appropriate to conduct a similar review of OTC drugs.

Cause for concern is illustrated by recent Drug Efficacy Study evaluations of the National Academy of Science-National Research Council. The NAS–NRC reviewed 420 OTC drugs which were broadly representative of the whole range of the OTC market. The NAS–NRC panels' conclusions, which were based upon supporting data submitted by manufacturers, were that approximately 25 percent of the drugs reviewed had an indication that was classifiable as effective. These evaluations, when viewed in the context of the entire OTC drug field, present questions that must be confronted by industry and government.

Estimates of the number of OTC drug products on the market vary from 100,000 to one-half million. Extremely few of these drugs have been approved through the new-drug procedures set forth in section 505 of the act. Some OTC drugs may be excluded from the definition of a new drug by reason of the so-called 1938 grandfather clause in section 201

(p)(1) of the act, and others may be excluded from application of the Drug Amendments of 1962 by reason of the so-called 1962 grandfather clause in section 107(c) of those amendments. Any OTC drug excluded from new-drug status by reason of the 1938 or 1962 grandfather clause is, however, subject to other requirements for drugs in Chapter V of the act, and in particular may not be misbranded under section 502.

The Food and Drug Administration intends to require that all unapproved new drugs and misbranded drugs either be reformulated and/or relabeled to meet all requirements of the act or be removed from the market. In carrying out its responsibilities in this area, the Food and Drug Administration may either initiate a separate court action with respect to each violative OTC drug or deal with all OTC drugs through rulemaking by therapeutic classes on an industrywide basis. It has been determined that the latter approach should be pursued. In making this decision, the following factors were considered:

1. The limited resources of the Food and Drug Administration would be overwhelmed by attempting to review separately the labeling and the data on the safety and effectiveness for each OTC drug now on the market. This would be further complicated by the almost daily growth in the number of drugs being marketed and the changes in formulation and labeling of previously marketed drugs. In large measure, this is the result of a tendency on the part of some manufacturers to develop new mixtures and adjust formulations and labeling for competitive reasons. The prospects of completing a detailed drug-by-drug review of the OTC market in a reasonable time are extremely remote.

2. Litigation to remove violative OTC preparations from the market would necessarily be on a drug-by-drug basis. Such proceedings would place an enormous burden on the courts which must hear the cases, on the agency which must prepare them, on the community of medical and scientific experts who must testify, and on the members of the pharmaceutical industry who are affected. Such litigation is time-consuming and expensive and is sometimes ineffective because manufacturers may change the formulation of the drug in question and/or its labeling claims and reintroduce the product into the market, thus requiring still further litigation.

3. Litigation to delineate the precise scope of the 1938 and 1962 grandfather clauses in order to determine exactly which of the thousands of OTC drugs on the market may validly claim exemption from new-drug status under those clauses and then to determine on a drug-by-drug basis which of those grandfathered claims and formulations are safe and effective under the prescribed, recommended, or suggested conditions of use, and thus not misbranded, would more than exhaust all present resources of the agency. There is no feasible way to determine what formulations and claims may properly be regarded as grandfathered, and in any event the date of entry into the market has no bearing whatever on the safety and effectiveness of the drug and the truthfulness and adequacy of its labeling. It would be unreasonable and unjust to permit grandfathered drugs to remain on the market unchanged while competitive items must be reformulated and/or relabeled or removed from the market. The same scientific and medical determinations involved in reviewing the safety and effectiveness of nongrandfathered OTC drugs are also involved in determining whether grandfathered drugs are misbranded and thus are properly made in a single proceeding that will apply across the board to all products in a single therapeutic class.

4. Of paramount concern is the inadequate consumer protection produced by a product-by-product review and case-by-case litigation against each drug. It is not unreasonable to expect that a very large number of violative drugs would remain on the market for long periods of time because of the limited resources of the agency to evaluate and proceed against such drugs and the delays inherent in complicated litigation through trial and appellate courts.

5. It is impossible to proceed simultaneously by litigation against all manufacturers of similar preparations or their drugs. The situation will arise, as it has before, that preparations similar to those proceeded against will remain on the market long after their less fortunate counterparts have been removed. This situation must be avoided for two reasons. First, and most important, the public is not sufficiently protected when violative drugs remain on the market. Second, equitable enforcement of the law requires that the agency proceed against all manufacturers of similar preparations, since those not proceeded against would have an unfair competitive advantage.

6. Practically all of the thousands of OTC drugs now marketed are compounded from only an estimated 200 active ingredients which are used either alone or in varying combinations. Many thousands of these drugs are readily comparable in that the labeling is similar and the active ingredients are the same, or are essentially the same, but are present in slightly different dosages. Although each is a separate product, the same scientific and medical evidence is relevant in reviewing all OTC drugs within a given therapeutic class.

7. Any approach to the review of the safety and effectiveness of OTC drugs must be consistent with the mandates of the Federal Food, Drug, and Cosmetic Act. In carrying out its responsibilities under the act through administrative proceedings and litigation in Federal courts, the agency has required the presence in published literature of adequate and appropriate medical documentation, consisting at least in part of controlled clinical investigations, as the test of whether a drug is no longer a new drug within the meaning of section 201 (p)(1) of the act. Unpublished and uncontrolled studies and data may corroborate published and controlled findings.

Accordingly, the Commissioner proposes to establish procedures for rule making which will result in classifying some OTC drugs as generally recognized among qualified experts as safe and effective and not misbranded under prescribed, recommended, or suggested conditions of use. Any OTC drug not meeting the requirements established for such drugs pursuant to this procedure will have to be the subject of an approved new-drug application prior to marketing. (Since a grandfathered drug that is found to be misbranded would be required to change its formulation and/or labeling and thus lose its grandfathered status, any such product must either meet the applicable monograph or be the subject of an approved new-drug application in order to be legally marketed.) A deviation from a monograph will be approved for an individual manufacturer through approval of a new-drug application justifying such a deviation. Shipment of a nonconforming OTC drug (one neither classified as generally recognized as safe and effective and not misbranded, nor subject to an approved NDA) in interstate commerce will be prohibited. Responsible persons and the manufacturer and distributor will be subject to criminal prosecution and injunctive action, and the drug will be subject to seizure and injunction on the ground that the drug is an unapproved new-drug or is a misbranded drug (if it is exempt from the new-drug definition under the 1938 or 1962 grandfather clause).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–42 as amended, 1050–53 as amended, 1055–56 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371) and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243 as amended; 5 U.S.C. 553, 702, 703, 704) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 130 be amended by adding a new Subpart D consisting at this time of one section, as follows:

Subpart D—Over-the-Counter Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded

§ 130.301 Over-the-counter (OTC) drugs for human use; procedures for rule making for the classification of OTC drugs as generally recognized as safe and effective and not misbranded under prescribed, recommended, or suggested conditions of use.

For purposes of classifying over-the-counter (OTC) drugs as drugs generally recognized among qualified experts as safe and effective for use and as not misbranded drugs, the following regulations shall apply:

(a) *Procedure for establishing OTC drug monographs*—(1) *Advisory review panels.* The Commissioner shall appoint advisory review panels of qualified experts to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise him on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. A single advisory review panel shall be established for each designated category of OTC drugs and every OTC drug category will be considered by a panel. The members of a panel shall be qualified experts (appointed by the Commissioner) and may include persons from lists submitted by organizations representing professional, consumer, and industry interests. The Commissioner shall designate the chairman of each panel. Summary minutes of all meetings shall be made.

(2) *Request for data and views.* The Commissioner will publish a notice in the FEDERAL REGISTER requesting interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of OTC drugs. Data and information submitted pursuant to a published notice, and falling within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331 (j), shall be handled by the advisory review panel and the Food and Drug Administration as confidential until publication of a proposed monograph and the full report(s) of the panel. Thirty days thereafter such data and information shall be made publicly available and may be viewed at the Office of the Hearing Clerk of the Food and Drug Administration, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of one or more of those statutes. To be considered, seven copies of the data and/or views on any marketed drug within the class must be submitted in the following format:

OTC DRUG REVIEW INFORMATION

I. Label(s) and all labeling.
II. A statement of the complete quantitative composition of the drug.
III. Animal safety data.
A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
IV. Human safety data.
A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.
C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of the finished drug product.
V. Efficacy data.
A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
VI. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the drug and its ingredients and the scientific basis (or lack thereof) for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

(3) *Deliberations of an advisory review panel.* An advisory review panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations to the Commissioner with respect to the safety and effectiveness of the drugs in a designated category of OTC drugs. A panel may consult any individual or group. Any interested person may request an opportunity to present oral views to the panel; such request may be granted or denied by th panel. Such requests for oral presentations should be in written form including a summarization of the data to be presented to the panel. Any interested person may present written data and views which shall be considered by the panel. This information shall be presented to the panel in the format set forth in subparagraph (2) of this paragraph and within the time period established for the drug category in the notice for review by a panel.

(4) *Standards for safety, effectiveness, and labeling.* The advisory review panel, in reviewing the data submitted to it and preparing its conclusions and recommendations, and the Commissioner, in reviewing the conclusions and recommendations of the panel and the published proposed, tentative, and final monographs, shall apply the following standards to determine general recognition that a category of OTC drugs is safe and effective and not misbranded:

(i) Safety means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability. Proof of safety shall consist of adequate tests by all methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use; such tests may be corroborated by reports of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

(ii) Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 130.12(a)(5)(ii), 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 is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. General recognition of effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

(iii) The benefit-to-risk ratio of a drug shall be considered in determining safety and effectiveness.

(iv) An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

(v) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary

individual, including individuals of low comprehension, under customary conditions of purchase and use.

(vi) A drug shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method of or collateral measures necessary to its use, it may safely be sold and used only under a practitioner's prescription.

(5) *Advisory review panel report to the Commissioner.* An advisory review panel shall submit to the Commissioner a report containing its conclusions and recommendations with respect to the conditions under which OTC drugs falling within the category covered by the panel are generally recognized as safe and effective and not misbranded. Included within this report shall be:

(i) A recommended monograph or monographs covering the category of OTC drugs and establishing conditions under which the drugs involved are generally recognized as safe and effective and not misbranded. This monograph may include any conditions relating to active ingredients, labeling indications, warnings and adequate directions for use, prescription or OTC status, and any other conditions necessary and appropriate for the safety and effectiveness of drugs covered by the monograph.

(ii) A statement of all active ingredients, labeling claims or other statements, or other conditions reviewed and excluded from the monograph on the basis of the panel's determination that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding.

(iii) A statement of all active ingredients, inactive ingredients, labeling claims or other statements, manufacturing procedures, or other conditions reviewed and excluded from the monograph on the basis of the panel's determination that the available data are insufficient to classify such conditions under either subdivision (i) or (ii) of this subparagraph and for which further testing is therefore required. The report may recommend the type of further testing required and the time period within which it might reasonably be concluded.

(6) *Proposed monograph.* After reviewing the conclusions and recommendations of the advisory review panel, the Commissioner shall publish in the FEDERAL REGISTER a proposed order containing:

(i) A monograph or monographs establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded.

(ii) A statement of the conditions excluded from the monograph on the basis of the Commissioner's determination that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding.

(iii) A statement of the conditions excluded from the monograph on the basis of the Commissioner's determination that the available data are insufficient to classify such conditions under either subdivision (i) or (ii) of this subparagraph.

(iv) The full report(s) of the panel to the Commissioner.

The proposed order shall specify a reasonable period of time within which conditions falling within subdivision (iii) of this subparagraph may be continued in marketed products while the data necessary to support them are being obtained for evaluation by the Food and Drug Administration. The summary minutes of the panel meetings shall be made available to interested persons upon request. Any interested person may, within 60 days after publication of the proposed order in the FEDERAL REGISTER, file with the Hearing Clerk of the Food and Drug Administration written comments in quintuplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the Office of the Hearing Clerk during regular working hours, Monday through Friday. Within 30 days after the final day for submission of comments, reply comments may be filed with the Hearing Clerk; these comments shall be utilized to reply to comments made by other interested persons and not to reiterate a position.

(7) *Tentative final monograph.* After reviewing all comments and reply comments, the Commissioner shall publish in the FEDERAL REGISTER a tentative order containing a monograph establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded. Within 30 days, any interested party may file with the Hearing Clerk of the Food and Drug Administration written objections specifying with particularity the omissions or additions requested. These objections are to be supported by a brief statement of the grounds therefor. A request for an oral hearing may accompany such objections.

(8) *Oral hearing before the Commissioner.* After reviewing objections filed in response to the tentative final monograph, the Commissioner, if he finds reasonable grounds in support thereof, shall by notice in the FEDERAL REGISTER schedule an oral hearing which shall last no longer than 3 hours. The notice scheduling an oral hearing shall specify the length of the hearing and how the time shall be divided among the parties requesting the hearing. The hearing shall be conducted by the Commissioner and may not be delegated.

(9) *Final monograph.* After reviewing the objections and considering the arguments made at any oral hearing, the Commissioner shall publish in the FEDERAL REGISTER a final order containing a monograph establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded. The monograph shall become effective as specified in the order.

(10) *Court appeal.* The monograph contained in the final order constitutes final agency action from which appeal lies to the courts. The Food and Drug Administration will request consolidation of all appeals in a single court. Upon court appeal, the Commissioner may, at his discretion, stay the effective date for part or all of the monograph pending appeal and final court adjudication.

(11) *Amendment of monographs.* The Commissioner may propose on his own initiative to amend or repeal any monograph established pursuant to this section. Any interested person may petition the Commissioner for such proposal. A petition shall set forth the action requested and a detailed statement of the grounds in support of such action. After review of a petition, the Commissioner may deny the petition if he finds a lack of substantial support for safety or effectiveness (in which case the appeal provisions of subparagraph (10) of this paragraph shall apply) or may publish a proposed amendment or repeal in the FEDERAL REGISTER if he finds substantial support for safety and effectiveness (in which case the provisions of subparagraphs (6), (7), (8), and (9) of this paragraph shall apply). A new-drug application may be submitted in lieu of or in addition to a petition under this paragraph.

(b) *Legal status of monographs.* (1) After its effective date, a monograph or any part thereof contained in a final order which is not the subject of a timely court appeal or which is the subject of a timely appeal and is affirmed by a court constitutes a binding substantive rule.

(2) Once a monograph or any part thereof becomes a binding substantive rule pursuant to subparagraph (1) of this paragraph, an OTC drug which falls within the category of drugs covered by that monograph shall be deemed not to be generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, unless it complies with all of the conditions established by that monograph.

(3) Once a monograph or any part thereof becomes a binding substantive rule pursuant to subparagraph (1) of this paragraph, an OTC drug which falls within the category of drugs covered by that monograph and which is exempt from the definition of a new drug in section 201(p)(1) of the act as a result of the so-called 1938 grandfather clause or which is not subject to the Drug Amendments of 1962 as a result of the so-called 1962 grandfather clause in section 107(c) of those amendments shall be deemed to be misbranded and in violation of section 502 of the act, unless it complies with all of the conditions established by that monograph.

(4) Once a monograph becomes a binding substantive rule pursuant to subparagraph (1) of this paragraph, an OTC drug falling within the category of drugs covered by that monograph shall, prior to its marketing, either comply with all of the conditions established in that

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monograph or be the subject of an approved new-drug application. Any such drug which fails to meet one or the other of these two conditions shall be in violation of the act and shall be subject to summary court procdeure for a determination of illegality. Persons and companies responsible for marketing a drug in violation of this provision are subject to criminal prosecution and injunction, and the violative drug is subject to seizure and injunction. The Commissioner will request recall of such products from the market.

(5) A new-drug application requesting approval of an OTC drug deviating in any respect from a monograph that has become a binding substantive rule pursuant to subparagraph (1) of this paragraph shall be in the form required by § 130.4(a)(2) but shall include a statement that the product meets all conditions of the applicable monograph except for the deviation for which approval is requested and may omit all information except that pertinent to the deviation for which approval is requested.

(c) The monographs promulgated pursuant to the provisions of this section shall be established in this Subpart D and shall consist of the following designated categories:

(1) Antacids.
(2) Laxatives.
(3) Antidiarrheal products.
(4) Emetics.
(5) Antiemetics.
(6) Antiperspirants.
(7) Sunburn prevention and treatment products.
(8) Vitamin-mineral products.
(9) Antiinfective products.
(10) Dandruff products.
(11) Mouthwash products.
(12) Hemorrhoidal products.
(13) Hematinics.
(14) Bronchodilator and antiasthmatic products.
(15) Analgesics.
(16) Sedatives and sleep aids.
(17) Stimulants.
(18) Antitussives.
(19) Antihistamines.
(20) Cold remedies.
(21) Antirheumatic products.
(22) Ophthalmic products.
(23) Contraceptive products.
(24) Menstrual products.
(25) Dentifrices and dental products such as analgesics, antiseptics, etc.
(26) Miscellaneous (all other OTC drugs not falling within one of the above therapeutic categories).

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: December 30, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-147 Filed 1-4-72;8:50 am]

Social Security Administration

[20 CFR Part 405]

[Reg. No. 5]

FEDERAL HEALTH INSURANCE FOR THE AGED

Provider Review Procedures and Suspension of Payments Under Medicare

Notice is hereby given, pursuant to the Administrative Procedure Act (5 U.S.C. 552 et seq.) that the amendments to the regulations set forth in tentative form below are proposed by the Commissioner of Social Security, with the approval of the Secretary of Health, Education, and Welfare. The proposed amendments (1) require intermediaries to institute review procedures for providers dissatisfied with intermediaries' determinations on cost reports; and (2) provide that payments to providers and suppliers of services could be suspended to recover overpayments to them only after such providers and suppliers have been afforded an opportunity to present evidence on the issue of the overpayment, and where a suspension of payments is put into effect there would be an expeditious settlement of the issues involved. It is intended that regulations dealing with provider reviews be effective for cost reporting periods ending on or after December 31, 1971, and that the regulations on suspensions be effective January 1, 1972.

Prior to the final adoption of the proposed amendments to the regulations, consideration will be given to any data, views, or arguments pertaining thereto which are submitted in writing in triplicate to the Commissioner of Social Security, Department of Health, Education, and Welfare Building, Fourth and Independence Avenue SW., Washington, DC 20201, within a period of 30 days from the date of publication of this notice in the FEDERAL REGISTER.

Copies of all comments received in response to this notice will be available for public inspection during regular business hours at the Washington Inquiries Section, Office of Public Affairs, Social Security Administration, Department of Health, Education, and Welfare, North Building, Room 3193, 330 Independence Avenue SW., Washington, DC 20201.

The proposed regulations are to be issued under the authority contained in sections 1102, 1815, and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 322, and 331, as amended; 42 U.S.C. 1302, 1395 et seq.

Dated: December 2, 1971.

ROBERT M. BALL,
Commissioner of Social Security.

Approved: December 29, 1971.

ELLIOT L. RICHARDSON,
Secretary of Health, Education, and Welfare.

Regulation No. 5 of the Social Security Administration (20 CFR Part 405) is further amended as follows:

1. The heading to Subpart C is revised to read as follows: Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer, and Suspension of Payment.

2. Section 405.301 is revised to read as follows:

§ 405.301 Scope of subpart.

Sections 405.310 to 405.320 describe certain exclusions from coverage applicable to hospital insurance benefits (part A of title XVIII) and supplementary medical insurance benefits (part B of title XVIII). The exclusions in this subpart are applicable in addition to any other conditions and limitations in this part 405 and in title XVIII of the Act. Sections 405.350 to 405.359 relate to the adjustment or recovery of an incorrect payment, or a payment made under section 1814(e) of the Health Insurance for the Aged Act. Sections 405.370 to 405.373 relate to the suspension of payments to a provider of services or other supplier of services where there is evidence that such provider or supplier has been or may have been overpaid.

3. New §§ 405.370–405.373 are added to read as follows:

§ 405.370 Suspension of payments to providers of services and other suppliers of services.

(a) Payments otherwise authorized to be made to providers of services and other suppliers of services in accordance with subpart A or subpart B of this part 405 (but excluding payments to entitled individuals and payments under § 405.251 (a)) may be suspended, in whole or in part, by an intermediary or a carrier when:

(1) The intermediary or carrier has determined that the provider or other supplier to whom such payments are to be made has been overpaid under title XVIII of the Social Security Act, or

(2) The intermediary or carrier has some evidence, although additional evidence may be needed for a determination, that such overpayment exists or that the payments to be made may not be correct.

(b) A suspension shall be put into effect only after the provisions in §§ 405.371 and 405.372 have been complied with and the intermediary or carrier has determined that the suspension of payments, in whole or in part, is needed to protect the program against financial loss. The provisions of this section and §§ 405.371–405.373 shall be effective on January 1, 1972.

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