interim collections have occurred must be maintained and preserved for at least 3 years after expiration.

(e) *Refund payment.* (1) Within 45 days after an eligibility determination that a first sale is not at least eligible for the price collected under this part becomes final, or an application for determination is withdrawn by an applicant while the application is before the Commission or the jurisdictional agency, the seller shall refund to the purchaser by cash or check the refund amount computed under paragraph (h) of this section together with interest determined in accordance with § 154.102(d), on the excess collections that have been collected from the date of payment until the date of refund.

(2) No interest is required to be paid on any portion of a refund:

(i) Which represents payments of royalties or taxes to Federal or State governmental authorities, except to the extent that such authorities pay interest to the seller when refunding overpayments of royalties or taxes; or

(ii) Which is paid from escrow except that interest which accrued in the escrow account on the amount required to be refunded shall be paid at the time of refund.

(f) *Filing requirements.* (1) Within 75 days of either the date a final determination of eligibility is obtained that a sale is not at least eligible for the price collected under this part, or the date the application for determination is withdrawn by the applicant while the application is before the Commission or the jurisdictional agency, the seller shall file with the Commission either:

(i) A refund report stating separately the amounts required to be refunded pursuant to paragraph (h) of this section and the appropriate interest to be paid thereon, in accordance with paragraph (e) of this section; or

(ii) A statement certifying that no refund payment is required pursuant to paragraph (e) of this section.

(2) A filing made pursuant to this paragraph shall include a statement of concurrence in the filing signed by the purchaser.

(g) *Discharge of obligation.* If an eligibility determination that natural gas is eligible for the price for which the application for determination was filed becomes final, then at such time, the bond, escrow, or undertaking shall be discharged to the extent it applies to first sales from the well for which the determination was made. If any refunds required by this section are made in conformity with the terms and conditions of the bond, escrow, or undertaking, the bond, escrow, or undertaking shall be discharged insofar as it applies to such refund obligation.

(h) *Refund computation.* (1) Where the final eligibility determination that the sale is not at least eligible for the price collected under Subpart B also includes a final eligibility determination of the maximum lawful price for that sale, that finally determined price, to the extent permitted by the applicable sales contract, shall be used to compute the excessive interim collections and refund amount.

(2) In any other case, the applicable maximum lawful price specified under Subpart D, E, F, or I of Part 271, to the extent permitted by the applicable sales contract, shall be used to compute the excessive interim collections and refund amount.

[FR Doc. 80-14676 Filed 5-12-80; 8:45 am]
BILLING CODE 6450-85-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 80N-0094]

Over-the-Counter (OTC) Category III Policy, Proposed Revised Rule

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the procedural regulations for reviewing and classifying over-the-counter (OTC) drugs to delete the provision that authorizes the marketing of a Category III ingredient or other condition in an OTC drug product after a final monograph. This revision will affect the time period during which testing may be completed and new data submitted to FDA to support the inclusion in a final monograph of a condition not classified in Category I in a proposed monograph or tentative final monograph. The agency is taking this action to conform to the court order issued by the District Court for the District of Columbia.

DATE: Comments by July 14, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: FDA is proposing to revise the OTC procedural regulations (21 CFR 330.10) to delete the provision that authorizes the marketing of a Category III ingredient or other condition in an OTC drug product after a final monograph is established. This action is being taken to conform to the holding and order of the United States District Court for the District of Columbia in *Cutler* v. *Kennedy,* 475 F. Supp. 838 (D.D.C. 1979). This revision will affect the time period during which testing may be completed and new data submitted to FDA to support the inclusion in a final monograph of those ingredients or other conditions not classified in Category I in a proposed monograph or tentative final monograph.

Current Procedure

The OTC drug review was instituted to carry out FDA's statutory mandate to assure that OTC drug products are safe and affective for their intended use and not misbranded. The current approach involves the development of drug "monographs," in the form of regulations, which define the conditions for which OTC drug products are generally recognized as safe and effective and not misbranded. Monographs list both acceptable ingredients and proper labeling for each of the different categories of OTC drug products. The procedures by which the monographs are developed involve several administrative steps, as set forth in 21 CFR 330.10. The Food and Drug Administration appointed scientific experts from outside the agency as members of advisory review panels. These panels were asked to review published and unpublished data and information, which the agency had requested interested persons to submit, that are pertinent to a designated category of OTC drug products. Each panel also includes two nonvoting liaison members, a representative of consumer interests and a representative of industry. Each panel reviews the data submitted and reports to the Commissioner of Food and Drugs its conclusions and recommendations as to the safety and effectiveness of ingredients and labeling in a designated category of drug products. Each panel report may include a recommended monograph establishing conditions under which the drug products involved are generally recognized as safe and effective and not misbranded (Category I). In addition, each panel report includes 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 a drug product not being generally recognized as safe and effective or would result in misbranding (Category II). (The wording "active ingredients, labeling claims or other statements, or other conditions" will herinafter be referred to as "conditions.") The report also includes a statement of all such conditions reviewed and excluded from the monograph on the basis of the panel's determination that the available data are insufficient to classify a condition as Category I or Category II and for which further testing is required (Category III). FDA publishes the panel reports and proposed monographs in the **Federal Register** and requests interested persons to comment within 90 days. Additionally, because new data may be submitted in those comments, the OTC drug regulations allow an additional 30 days after the comment period for the filing of reply comments. After considering these comments and reply comments, the agency publishes a tentative order proposing a monograph in the form of a regulation, which is subject to public objections and requests for a hearing for a period of 30 days. If the Commissioner finds reasonable grounds for so doing, an oral hearing before the Commissioner may be scheduled. At the conclusion of these procedures, the agency publishes an order issuing a final monograph. After publication of a final monograph, any product with a Category III condition may remain on the market or may be introduced into the market, provided each sponsor of a study notifies FDA that studies will be undertaken to obtain the data necessary to resolve the issues that resulted in such classification. When FDA issued the OTC drug regulations, it concluded that Category III testing should not be required until after completion of the established OTC drug administrative procedures. Because an opportunity for public review and comment is provided at each stage of the administrative procedure, the content of Category III and the testing period provided are not fixed until publication of the final monograph. Some manufacturers, however, have begun the testing of Category III conditions voluntarily before FDA has issued a final OTC drug monograph.

Court Opinion

On July 16, 1979, the United States District Court for the District of Columbia entered its opinion in the case of *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). Plaintiffs had alleged that 21 CFR 330.10 is unlawful to the extent that it authorizes the marketing of Category III drugs after publication of a final monograph. Plaintiffs claimed that, if a drug is determined to be in Category III, it necessarily lacks substantial evidence of safety or effectiveness, is a new drug, and cannot be marketed without an approved NDA. The Court concluded that "* * * the FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions * * * are exempted from enforcement action," (*Cutler, supra* at 856). The Court issued an order that declared the OTC drug regulations, 21 CFR 330.10, unlawful to the extent that they authorize the marketing of Category III drugs after a final monograph, and enjoined the FDA from implementing any portion of the regulations that authorizes such marketing.

Proposed Revised Requirements

Testing of Category III Conditions

Section 330.10(a)(13) (21 CFR 330.10(a)(13)) sets forth the conditions under which an OTC drug product with a condition classified in Category III may continue to be marketed after publication of a final monograph pending development of data to support approval of the condition as safe, effective, and not misbranded. The Court has declared that this provision of the OTC drug regulations is unlawful. Therefore, the agency proposes to delete § 330.10(a)(13) in its entirety. Any testing necessary to resolve the safety or affectiveness issues that formerly resulted in a Category III classification and submission to FDA of the results of that testing or any other data must be done during the OTC drug rulemaking process, before the establishment of a final monograph. Data submitted prior to the publication of a final order but after the administrative record has closed must be in the form of a petition to amend the final monograph.

The agency advises that tentative final and final monographs will no longer contain recommended testing guidelines. However, the agency will meet with industry representatives, at their request, to provide information on data already submitted to FDA, to develop testing guidelines for those conditions which industry is interested in upgrading, and to advise industry on the adequacy of their proposed protocols. Any communications between FDA and industry on these matters may continue outside the formal comment periods, and such communications will be part of the public record. FDA continues to encourage firms to cooperate and work with each other in arranging for the necessary study or studies to avoid unnecessary and repetitive human testing.

Contents and Time of Closing of the Administrative Record

Currently, under § 330.10(a)(10)(i) the administrative record closes at the end of the comment period following publication of the panel report with respect to the submission of new data and information for consideration by the agency in developing a tentative final monograph. Thereafter, no new data and information can be submitted for inclusion in the administrative record except with a petition to the Commissioner requesting that the administrative record be reopened to include such material. Because manufacturers must, in the future, submit before the final monograph, the data necessary to resolve the issues that previously resulted in a Category III classification, the agency proposes to provide for a fixed time period after a tentative final monograph during which manufacturers may submit new data and information to support approval of a condition as safe, effective, and not misbranded. In addition, the agency proposes to redesignate the contents of and time of closing of the administrative record in § 330.10(a)(10).

This action is being taken for a number of reasons. Substantial numbers of tests aimed at upgrading Category III conditions to Category I have already been completed and the results have been submitted to the agency for evaluation and review prior to publication of the relevant tentative final monograph. Those data were developed under the testing guidelines developed by various Panels and published in the Panel's report. As agency scientists have begun to evaluate the data, they have found that, in some cases, certain additional information is necessary to enable them to complete their review. Were the administrative record to remain closed, each particle of new information would have to be submitted with a petition to reopen the administrative record. Each of these petitions would then have to be reviewed, and either granted or denied, entailing additional burdensome administrative effort by the agency. Further, as agency scientific personnel meet with industry representatives in informal meetings to discuss future testing requirements, an open administrative record makes it much less cumbersome and time-consuming to submit the additional data and information that FDA has determined are necessary to upgrade the conditions. In addition, manufacturers will in the future have to submit data necessary to

resolve issues of safety, effectiveness, and misbranding before publication of a final monograph. Leaving the record open will facilitate this process.

Finally, by permitting the record to remain open, the agency believes that it can facilitate the entire review and accord the various matters the type of attention required—scientific, policy, and legal—in the most efficient fashion possible. After a tentative final monograph has been published, the agency must expend a substantial amount of time reviewing and responding to objections, comments on new data, and requests for hearings. This administrative review is distinct from the scientific evaluation of the new data, but the both kinds of scrutiny must be completed before any final rule is issued. Based on the agency's experience with comments filed to Panel Reports and with the tentative final and final monographs published to date, the evaluation of the comments, objections, and requests for hearings will take at least as long as the fixed time period established for the submission of new data. Thus, leaving the record open for new data will not, in the agency's judgment, delay the overall process because this period is necessary in any event to complete the essential task of evaluating the comments.

Under the proposed revisions, the agency's decision in a tentative final monograph will be based solely on the administrative record developed through the 90-day comment and 30-day rebuttal comment period. New data and information may be submitted after the 90-day comment period but will not be included as part of the administrative record for consideration by the agency until after the administrative record is reopened following publication of a tentative final monograph, as discussed below.

After publishing a tentative final monograph in the **Federal Register**, FDA proposes to reopen the administrative record for 12 months to permit interested persons to submit new data and information in support of the safety and effectiveness of any condition reviewed by a panel and not classified in Category I, and for an additional 2 months to permit interested persons to submit written comments on any new data and information submitted through the 12-month period. Section 330.10(a)(7) and (10) has been revised accordingly. The agency's decision on the conditions to be included in a final monograph will be based solely on the administrative record developed throughout the entire OTC drug rulemaking period, i.e., through the 14-month period following publication of the tentative final monograph including the 12 months for the submission of new data and the 2-month comment period on that date. Data received by FDA after the closing of the administrative record will be treated after publication of the final monograph as a petition to amend the monograph. The Food and Drug Administration will not include such data in its consideration of the content of a final monograph.

Additionally, FDA proposes to extend the period for filing written objections following publication in the **Federal Register** of a tentative final monograph to 60 days to permit additional time for interested persons to fully evaluate the agency's position on a panel's recommendations. Section 330.10(a)(7) has been revised accordingly.

The agency further proposes to delete the petition procedure described in § 330.10(a)(10)(ii) because it duplicates the provisions of § 10.30 (21 CFR 10.30) of the agency's procedural regulations concerning petitions. The agency also proposes to delete § 330.10(a)(12)(i) because the provisions are no longer relevant. The agency advises that revision of § 330.10(a)(12)(ii) (concerning FDA's acceptance of a new drug application for a condition in the OTC drug review) is being contemplated and any revision, if proposed, will be published in a future **Federal Register** statement.

Category II Conditions

Under the current OTC drug review procedures, all conditions reviewed by a panel within a specific category of drugs experience the same total lapsed time between adoption of a panel report and publication of a final monograph regardless of their classification. The agency intends to reduce the time period for those Category II active ingredients on which no substantive comments have been received. Therefore, the agency proposes to revise § 330.10(a)(7) to provide that the Commissioner may publish a separate tentative order for any ingredient classified by a panel in Category II and for which no substantive comments in opposition to the panel report or new data and information were submitted within the 90-day comment period following publication in the **Federal Register** of a panel report. Further, following publication of a tentative order, any interested person may file with the Hearing Clerk written objections to provisions of the order and request an oral hearing. If no objections are received and there are no requests for an oral hearing, the agency would proceed directly to a final order. The agency believes this revised procedure would serve the public interest because it would expedite completion of the OTC drug review and removal from the market of those ingredients for which the Category II classification has evoked no comments.

OTC Drug Review Classification Terminology

Although the classification terminology used during the pendency of the OTC drug rulemaking proceeding was not involved in the court proceedings in *Cutler*, FDA is proposing to abandon the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" and "nonmonograph conditions." That is, a "monograph condition" would be any condition included in a monograph which the agency publishes in the **Federal Register** as part of a final order. Any condition excluded from the monograph for a specific category of drug products would be termed a "nonmonograph condition" regardless of the reason for its exclusion from the monograph. The preamble to the final order would use this term in stating those conditions included in the OTC drug review but excluded from the monograph. The agency concludes that this proposed language reflects the court's decision that only OTC drug products meeting the conditions of a monograph or having an approved new drug application (NDA) may be legally marketed after a monograph is final. Any OTC drug product containing a "nonmonograph condition" would be subject to regulatory action as specified below.

Regulatory Policy

Any currently marketed OTC drug product that fails to conform to an applicable monograph after its effective date, and that is not covered by an approved new drug application, is subject to regulatory action. The agency has developed a general enforcement policy that will enable it to take regulatory action in an orderly fashion, commensurate with availabe resouces, against those OTC drug products failing to meet the requirements of an applicable monograph. This policy is consistent with enforcement policies for prescription new drug products, e.g., FDA Compliance Policy Guide 7132c.08 dated October 6, 1976, which is designed to deal on a priority basis with marketed new drugs without approved new drug applications. The policy is intended to give first attention to those products that most affect the public health and safety, to provide equitable treatment among

competing firms, and to utilize agency resources most efficiently.

The broad enforcement priorities established by FDA for initiating regulatory action against those marketed OTC drug products that fail to meet the monograph conditions are, in order of priority, as follows:

1. Products that present a potential health hazard.

2. Products that contain either (1) an ingredient excluded from the monograph because the ingredient is not generally recognized as safe or (2) a claim excluded from the monograph on the basis that the claim's use would result in the products not being generally recognized as safe.

3. Products that contain an ingredient excluded from the monograph because the ingredient is not generally recognized as effective.

4. Products that contain an ingredient or claim excluded from the monograph because of insufficient information and for which no petition to amend the monograph is pending before the agency.

5. Products that contain monograph ingredients but that fail to meet the conditions of the monograph in other respects, e.g., its label fails to contain required information, the product fails to pass required *in vitro* tests, or its labeling contain claims excluded from the monograph on the basis that the claims would result in the product not being generally recognized as effective.

6. Products similar to those described in number 4 above except that a full and complete petition to amend the monograph to include the ingredient or claim in the monograph is pending before the agency.

7. Products that contain a nonmonograph ingredient or claim for which there is a pending NDA before the agency.

Petitions and NDA's pending before the agency as described in paragraphs (6) and (7) above will be given a preliminary review by FDA upon receipt to be certain that they are full and complete.

As explained above, these priorities constitute the agency's current views about how best to use available resources consistent with its obligation to protect the public health. That FDA is attempting to allocate its resources as efficiently as possible does not mean that it will neglect any matter that significantly affects the consumer. For example, the agency reiterates that it will continue to take regulatory action at any time in the review against products that present a potential health hazard or a significant and substantial effectiveness question. Further, the agency is prepared to take enforcement action against products that are adulterated or misbranded in ways not directly related to the OTC review process, e.g., failure to bear label warnings presently required by other regulations.

Most important, FDA wishes to emphasize that this policy and the priorities described above are part of an overall approach to enforcement action. Like other policies it is subject to change, depending on various factors existing in the market place. Accordingly, this regulatory policy is not necessarily a final and comprehensive statement of FDA's enforcement posture with respect to all aspects of OTC drug compliance, and its issuance does not preclude the agency from modifying or amplifying it at a later date, with or without public notice.

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701(a), 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055 (21 U.S.C. 321, 352, 355, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 330 be amended in § 330.10 by revising paragraph (a) (7), (9), (10), and (12) and by deleting paragraph (a)(13) as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

* * * * *

(a) * * *

(7) *Tentative final monograph.* (i) After reviewing all comments, reply comments, and any new data and information, 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 60 days, any interested person may file with the Hearing Clerk, 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.

(ii) The Commissioner may publish in the **Federal Register** a separate tentative order containing a statement of those active ingredients reviewed and proposed to be excluded from the monograph on the basis of the Commissioner's determination that they would result in a drug product not being generally recognized as safe and effective or would result in misbranding, and for which no substantive comments in opposition to the panel report or new data and information were received by the Food and Drug Administration pursuant to paragraph (a)(6)(iv) of this section. Within 60 days, any interested person may file with the Hearing Clerk, Food and Drug Administration, written objections specifying with particularity the provision of the tentative order to which objection is made. These objections are to be supported by a brief statement of the grounds therefor. A request for an oral hearing may accompany such objections.

(iii) Within 12 months after publishing a tentative order pursuant to paragraph (a)(7)(i) of this section, any interested person may file with the Hearing Clerk, Food and Drug Administration, new data and information to support a condition excluded from the monograph in the tentative order.

(iv) Within 60 days after the final day for submission of new data and information, comments on the new data and information may be filed with the Hearing Clerk, Food and Drug Administration.

(v) New data and information submitted after the time specified in this paragraph but prior to the establishment of a final monograph will be considered as a petition to amend the monograph and will be considered by the Commissioner only after a final monograph has been published in the **Federal Register.**

* * * * *

(9) *Final monograph.* After reviewing the objections, the entire administrative record including all new data and information and comments, 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) *Administrative record.* (i) All data and information to be considered in any proceeding pursuant to this section shall be submitted in response to the request for data and views pursuant to

paragraph (a)(2) of this section or accepted by the panel during its deliberations pursuant to paragraph (a)(3) of this section or submitted to the Hearing Clerk as part of the comments during the 90-day period and 30-day rebuttal comment period permitted pursuant to paragraph (a)(6) of this section or submitted to the Hearing Clerk during the 12-month period or as part of the comments during the 60-day period permitted pursuant to paragraph (a)(7) of this section.

(ii) The Commissioner shall make all decisions and issue all orders pursuant to this section solely on the basis of the administrative record, and shall not consider data or information not included as part of the administrative record.

(iii) The administrative record shall consist solely of the following material: All notices and orders published in the **Federal Register,** all data and views submitted in response to the request published pursuant to paragraph (a)(2) of this section or accepted by the panel during its deliberations pursuant to paragraph (a)(3) of this section, all minutes of panel meetings, the panel report(s), all comments and rebuttal comments submitted on the proposed monograph and all new data and information submitted pursuant to paragraph (a)(6) of this section, all objections submitted on the tentative final monograph and all new data and information and comments submitted pursuant to paragraph (a)(7) of this section, the complete record of any oral public hearing conducted pursuant to paragraph (a)(8) of this section, all other comments requested at any time by the Commissioner, all data and information for which the Commissioner has reopened the administrative record, and all other material that the Commissioner includes in the administrative record as part of the basis for the Commissioner's decision.

* * * * *

(12) *Amendment of monographs.* (i) The Commissioner may propose on the Commissioner's own initiative to amend or repeal any monograph established pursuant to this section. Any interested person may petition the Commissioner for such proposal pursuant to § 10.30 of this chapter. The Commissioner may deny the petition if the Commissioner finds a lack of safety or effectiveness employing the standards in paragraph (a)(4) of this section (in which case the appeal provisions of paragraph (a)(11) of this section shall apply), or the Commissioner may publish a preposed amendment or repeal in the **Federal Register** if the Commissioner finds general recognition of safety and effectiveness employing the standards in paragraph (a)(4) of this section. Any interested person may, within 60 days after publication of the proposed order in the **Federal Register,** file with the Hearing Clerk, Food and Drug Administration, written comments in quadruplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed in the office of the Hearing Clerk between the hours of 9 a.m. and 4 p.m., Monday through Friday. After reviewing the comments, the Commissioner shall publish a final order amending the monograph established under the provisions of paragraph (a)(9) of this section or withdraw the proposal if comments opposing the amendment are persuasive. A new drug application may be submitted in lieu of, or in addition to, a petition under this paragraph.

(ii) A new drug application may be submitted in lieu of a petition to amend the OTC drug monograph only if the drug product with the condition that is the subject of the new drug application has not been marketed on an interim basis (such as under the provisions of paragraph (a)(6)(iii) of this section), all clinical testing has been conducted pursuant to a new drug application plan, and no marketing of the product with the condition for which approval is sought is undertaken prior to approval of the new drug application. The Food and Drug Administration shall handle a new drug application as a petition for amendment of a monograph, and shall review it on that basis, if the provisions of this paragraph preclude approval of a new drug application but permit the granting of such a petition.

* * * * *

Interested persons may, on or before July 14, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: May 6, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80–14637 Filed 5–12–80; 8:45 am]

BILLING CODE 4110–03–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 70, 71, 90

Respirable Dust; Additional Public Hearings on Miner Participation

AGENCY: Mine Safety and Health Administration, Department of Labor.

ACTION: Notice of additional public hearings.

SUMMARY: Public hearings will be held in four locations, in addition to those previously announced in the **Federal Register** on April 8, 1980, in order to receive testimony on the proposed provisions involving miner participation in respirable dust sampling procedures. The miner participation issue will be the only issue covered at the new hearings and will not be covered at the earlier hearings on June 3 and 5, 1980.

DATES: The additional public hearings will be conducted on the following dates:

July 8, 1980—Pittsburgh, Pennsylvania.

July 8, 1980—Lexington, Kentucky.

July 10, 1980—Charleston, West Virginia.

July 10, 1980—Denver, Colorado.

Requests to make oral statements for the record at these hearings should be submitted in writing by July 3, 1980. The rulemaking record for the miner participation proposals only will remain until July 24, 1980.

ADDRESSES: Send requests to make oral statements to the Mine Safety and Health Administration, Office of Standards, Regulations and Variances, Room 631, 4015 Wilson Boulevard, Arlington, Virginia 22203.

The four public hearings will be held beginning at 9:00 a.m. at the following locations:

U.S. Bureau of Mines Building, Auditorium, First Floor, 4800 Forbes Avenue, Pittsburgh, Pennsylvania 15213.

Holiday Inn North, Burley Room, I–75 and Newtown Pike, Lexington, Kentucky 40505.

University of Charleston, Geary Student Union Building, Ballroom, Third Floor, 2300 MacCorkle Avenue, SE., Charleston, West Virginia 25304.