VETERANS ADMINISTRATION

STATION COMMITTEE ON EDUCATIONAL ALLOWANCES

Meeting

Notice is hereby given pursuant to Section V, Review Procedure and Hearing Rules, Station Committee on Educational Allowances that on February 28, 1977, at 9:00 AM, the Portland, Oregon Regional Office Station Committee on Educational Allowances shall at Room 1376, Federal Building, 1220 SW 3rd Avenue, Portland, Oregon, conduct a hearing to determine whether Veterans Administration benefits to all eligible persons enrolled in Oregon Polytechnic Institute, Portland, Oregon, should be discontinued, as provided in 38 C.F.R. 21.4134, because a requirement of law is not being met or a provision of the law has been violated. All interested persons shall be permitted to attend, appear before, or file statements with the committee at that time and place.

Dated: January 26, 1977.

DONNA M. ARNDT,
Director, VA Regional Office.

[FR Doc.77-3628 Filed 2-3-77;8:45 am]

INTERSTATE COMMERCE COMMISSION

[Notice No. 318]

ASSIGNMENT OF HEARINGS

FEBRUARY 1, 1977.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notice of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

AB-19 (Sub-No. 19), Baltimore and Ohio Railroad Company Abandonment Portion of the Ohio and Little Kanawha Branch Between Relief and Philo, in Muskingum, Morgan and Washington Counties, Ohio, continued to March 9, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 124211 (Sub-No. 278), Hilt Truck Line, now assigned February 1, 1977, at Washington, D.C. is canceled and application dismissed.

MC 119988 (Sub-No. 94), Great Western Trucking Co., Inc., now assigned March 14, 1977, at Denver, Colo. will be held in Room 595, Federal Courthouse, 1961 Stout Street.

MC 107452 (Sub-No. 5), R. D. Brown DBA Dan Brown Trucking, now assigned March 15, 1977, at Denver, Colo. will be held in Room 595, Federal Courthouse, 1961 Stout Street.

MC 115904 (Sub-No. 45), Grover Trucking Co., now assigned March 17, 1977, at Denver, Colo. will be held in Room 595, Federal Courthouse, 1961 Stout Street.

MC 113678 (Sub-No. 633), Curtis, Inc., now assigned March 16, 1977, at Denver, Colo. will be held in Room 595, Federal Courthouse, 1961 Stout Street.

MC-F 12826, F-B Truck Line Company—Purchase (Portion)—Archer Freight Lines, Inc., MC 124533 (Sub-No. 69), F-B Truck Line Company, MC-F-12827, Lester Smith Trucking, Inc.—Purchase (Portion)—Archer Freight Lines, Inc. and MC 57697 (Sub-No. 2), Lester Smith Trucking, Inc., now assigned March 21, 1977, at Denver, Colo. will be held in Room 595, Federal Courthouse, 1961 Stout Street.

MC 134922 (Sub-192), B. J. Mcadams, Inc., now assigned March 15, 1977 at Columbus, Ohio, will be held in Room 235, Federal Office Building, 85 Marconi Boulevard.

MC 134150 (Sub-7), Southwest Equipment Rental, Inc., d/b/a Southwest Motor Freight, now assigned March 16, 1977 at Columbus, Ohio, will be held in Room 235, Federal Office Building, 85 Marconi Boulevard.

MC 115841 (Sub-522), Colonial Refrigerated Transportation, Inc., now assigned March 21, 1977 at Cincinnati, Ohio, will be held in Room 5008, Federal Office Building, 550 Main Street.

MC 83539 (Sub-No. 445), C & H Transportation Co., Inc.; MC 106497 (Sub-No. 136), Parkhill Truck Company; MC 114273 (Sub-No. 272) CRST, Inc.; MC 117574 (Sub-No. 279), Dailey Express, Inc.; MC 127820 (Sub-No. 8), Trans-Service, Inc. and MC 136828 (Sub-No. 12), Cooks Transports, Inc., now being assigned March 17, 1977 (2 days), at Columbus, Ohio; in Room 235 Federal Office Building, 85 Marconi Boulevard.

MC 138875 Sub 29, Shoemaker Trucking Company now assigned February 1, 1977 at Boise, Idaho is cancelled, application dismissed.

MC 41406 (Sub-54), Artim Transportation System, Inc.; MC 95876 (Sub-188), Anderson Trucking Service, Inc.; MC 106674 (Sub-208), Schilli Motor Lines, Inc.; MC 112304 (Sub-111), Ace Doran Hauling & Rigging Co.; MC 117068 (Sub-70), Midwest Specialized Transportation, Inc.; MC 119774 (Sub-90), Eagle Trucking Company MC 120737 (Sub-40), Star Delivery & Transfer, Inc.; MC 123407 (Sub-313), Sawyer Transport, Inc.; MC 138144 (Sub-12), Fred Olson Co., Inc. and MC 138741 (Sub-22), E. K. Motor Service, Inc., now assigned March 17, 1977 at Columbus, Ohio, will be held in Room 235 Federal Office Building, 85 Marconi Boulevard.

MC 119789 Sub 307, Caravan Refrigerated Cargo, Inc. now being assigned March 22, 1977 (1 day) at New York, New York in a hearing room to be later designated.

MC 142398, East Forward, Inc. now assigned March 22, 1977 at New York, New York is cancelled, application dismissed.

MC-F 12974, Takin Bros. Freight Lines, Inc.—Purchase (Portion)—Chi-Fil, Inc. now assigned February 14, 1977 at Chicago, Illinois is now cancelled indefinitely.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-3663 Filed 2-3-77;8:45 am]

federal register

FRIDAY, FEBRUARY 4, 1977

PART II

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

DEPARTMENT OF AGRICULTURE

Forest Service

■

GRAZING FEE TASK FORCE

Charter and Requests for Comments

DEPARTMENT OF AGRICULTURE

Forest Service

GRAZING FEE TASK FORCE

Charter and Requests for Comments

CROSS REFERENCE: For a document issued jointly by the Department of Agriculture's Forest Service and the Department of the Interior's Bureau of Land Management on the subject of Grazing Fee Task Force Charter, see FR Doc. 77-3310 appearing in Part II of this issue.

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

GRAZING FEE TASK FORCE

Charter and Request for Comments

Notice is hereby given that the Bureau of Land Management, Department of the Interior, and the Forest Service, Department of Agriculture, have jointly established a task force to study fees for grazing livestock on Federal lands the two agencies administer, and to prepare a report and recommenations. The purpose is to advise the public of the charter of the Grazing Fee Task Force and of the intent to request comments on grazing fees.

CHARTER OF GRAZING FEE TASK FORCE

In compliance with Section 401(a) of Pub. L. 94-579, a joint Bureau of Land Management and Forest Service Grazing Fee Task Force, will preare the "Report of the Secretaries" for submission to the Congress on or before October 21, 1977.

TASK FORCE STAFF

Co-chairman:
William L. Evans, Director of Range Management, Forest Service, Department of Agriculture.
Kay W. Wilkes, Chief, Division of Range, Bureau of Land Management, Department of the Interior.
Members:
Melvin D. Bellinger, Forst Service.
Ronald J. Younger, Bureau of Land Management.
Consultant:
Economic Research Service, Department of Agriculture.

STATEMENT OF AUTHORITY

Section 401(a) of the Federal Land Policy and Management Act of 1976 (Pub. L. 94-579), directs the Secretary of Agriculture and the Secretary of the Interior to jointly conduct a study to determine the value of grazing with a view to establishing a fee to be charged for livestock grazing which is equitable to the United States and to holders of grazing permits and leases. The Secretaries shall report to the Congress by October 21, 1977, the results of such study together with recommendations to implement a reasonable grazing fee schedule based on such study.

A letter dated December 29, 1976, and signed by the Assistant Secretary of the Interior and the Assistant Secretary of Agriculture, directed the Bureau of Land Management and the Forest Service to organize a Grazing Fee Task Force to prepare the "Report of the Secretaries."

The Economic Research Service, Department of Agriculture, will be a consultant to the Grazing Fee Task Force. Staff assigned by the Administrator of the Economic Research Service will participate in the collection and review of public comments and will provide advice on methodology, on evaluation of data, and on economic issues.

The task force co-chairmen are authorized to solicit assistance and advice from other sources as necessary.

STATEMENT OF ASSIGNMENT

The task force is assigned the responsibility for the accomplishment of all activities necessary to submit to the two Secretaries a grazing fee report, including recommendations, that will fulfill the requirements of Section 401(a) of the Federal Land Policy and Management Act. These activities include scheduling regional public meetings, obtaining necessary technical data, public release of the Technical Committee report, "Review of Public Land Grazing Fees," consultation with the Office of Management and Budget, and reporting back to the Assistant Secretary of the Interior for Land and Water Resources and the Assistant Secretary of Agriculture for Conservation, Research, and Education by August 1, 1977.

The Grazing Fee Task Force shall terminate not later than December 21, 1977.

The charter of the Grazing Fee Task Force is approved by:

Dated: January 28, 1977.

JOHN R. MCGUIRE,
Chief, Forest Service.

CURT BERKLUND,
Director, Bureau of Land Management.

REQUEST FOR COMMENTS

Pursuant to the charter, notice is given of intent to solicit suggestions, comments, statements, and recommendations from all parties interested in the establishment of fees for grazing livestock on the Federal lands in the western States administered by the Forest Service, Department of Agriculture, and the Bureau of Land Management, Department of the Interior. Any individual desiring to present data, suggestions, comments, and/or arguments orally may do so within available time limits at one of the scheduled meetings. Any interested person or organization may file a written statement with the task force at the scheduled meetings.

The Grazing Fee Task Force will consider comments regarding grazing fees on the following Federal lands:

1. Public lands administered by the Bureau of Land Management, Department of the Interior.

2. National Forest lands in the eleven contiguous western States administered by the Forest Service, Department of Agriculture.

3. National Forest lands in South Dakota and Nebraska administered by the Forest Service.

4. All National Grasslands administered by the Forest Service.

Interested persons may submit written comments on grazing fees on or before April 8, 1977. Written communications should be directed to the Grazing Fee Task Force, Range Management Staff, P.O. Box 2417, Washington, D.C. 20013, or presented at any one of the seven scheduled public meetings. All Comments received will be available for public inspection during regular business hours in Room 610, 1621 North Kent Street, Arlington, Virginia, or in Room 5558, Department of the Interior Building, 17th and D Street, Washington, D.C.

The public meetings are scheduled at the locations and dates listed below during the hours of 9:30 a.m., to 3:00 p.m.

Rapid City, S. Dak	Mar. 7, 1977
Missoula, Mont	Mar. 9, 1977
Boise, Idaho	Mar. 11, 1977
Reno, Nevada	Mar. 14, 1977
Denver, Colo	Mar. 16, 1977
Albuquerque, N. Mex	Mar. 18, 1977
Washington, D.C	Mar. 23, 1977

Further information about meeting locations may be obtained from the Bureau of Land Management or Forest Service offices in the cities listed above.

INFORMATION AVAILABLE

Special attention is directed to the following provisions of the Federal Land Policy and Management Act of 1976 (Pub. L. 94-579);

SECTION 102(a). The Congress declares that it is the policy of the United States that * * *

(9) The United States receive fair market value of the use of the public lands and their resources unless otherwise provided for by statute;

SECTION 401(a). The Secretary of Agriculture and the Secretary of the Interior shall jointly cause to be conducted a study to determine the value of grazing on the lands under their jurisdiction in the eleven western States with a view to establishing a fee to be charged for domestic livestock grazing on such lands which is equitable to the United States and to the holders of grazing permits and leases on such lands. In making such study, the Secretaries shall take into consideration the costs of production normally associated with domestic livestock grazing in the eleven western States, differences in forage values, and such other factors as may relate to the reasonableness of such fees. The Secretaries shall report the result of such study to the Congress not later than one year from and after the date of approval of this Act, together with recommendations to implement a reasonable grazing fee schedule based upon such study. If the report required herein has not been submitted to the Congress within one year after the date of approval of this Act, the grazing fee charge then in effect shall not be altered and shall remain the same until such report has been submitted to the Congress. Neither Secretary shall increase the grazing fee in the 1977 grazing year.

REPORT: "REVIEW OF PUBLIC LAND GRAZING FEES"

The Technical Committee report, "Review of Public Land Grazing Fees" was submitted in November 1976, in fulfillment of the Memorandum of Understanding signed in July 1976 between the Bureau of Land Management, Forest Service, Economic Research Service, and Statistical Reporting Service. We believe the report will fulfill the study requirements of Section 401(a) of Pub. L. 94-579. The report is expected to be a primary document used by the Grazing Fee Task Force and is being published here for the convenience of interested individuals and/or organizations that may desire to submit written comments regarding the "Review of Public Land Grazing Fees." The publication of the "Review of Public Land Grazing Fees" does not constitute approval of the report's recommendations by the Secretary of the Interior or Secretary of Agricul-

ture. Issued in Washington, D.C., January 27, 1977, by the Chief, Forest Service and Director, Bureau of Land Management.

Dated: January 28, 1977.

JOHN R. MCGUIRE,
Chief, Forest Service.

CURT BERKLUND,
Director, Bureau of Land Management.

REVIEW OF PUBLIC LAND GRAZING FEES: NOVEMBER 15, 1976

A report prepared by the Technical Committee organized to review public land grazing fees, Department of the Interior, Bureau of Land Management, and Department of Agriculture, Economic Research Service, Statistical Reporting Service and the Forest Service.

REVIEW OF PUBLIC LAND GRAZING FEES: NOVEMBER 15, 1976

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TECHNICAL COMMITTEE MEMBERS

Dr. John Trierweiler, Chairman; Economic Research Service, USDA.
Melvin D. Bellinger; Forest Service, USDA.
James L. Olsen; Statistical Reporting Service, USDA.
Ronald J. Younger; Bureau of Land Management, USDI.

SUMMARY

The Technical Committee to Review Public Land Grazing Fees was formed by a Memorandum of Understanding on July 12, 1976 between ERS, USDA; SRS, USDA; FS, USDA; and BLM, USDI. The committee was formed to prepare a report on "Public Land Grazing Fees." The specific tasks of the Technical Committee were:

A. To examine the present procedures for establishing grazing fees.

B. To examine the several alternatives which have been proposed as replacement or modification for all or portions of present procedure.

C. Identify available or additional secondary data which might enhance the present or alternatives procedures for determining fees.

The review was conducted within existing administrative mandates that a fair market value fee must be collected and that permit value would not be considered a valid cost factor for determining public land grazing fees.

In order that the review be helpful in resolving, or reducing the controversy about grazing fees, two meetings were held so that the various interest groups could present their views on the public land grazing fee issue, suggested alternatives, and factors to be considered and/or clarified.

Evaluation of the existing system of fee determination or the suggested alternatives requires a criteria for comparison. Although there is no obvious way to determine what is "fair," it can be shown that the competitive norm satisfies the conditions of a welfare ideal. Few economists would claim that pure competition does or ever has existed, but it does provide a logical starting place for evaluation of great many economic problems. The competitive norm incorporates the efficiency concept of equimarginal resource returns, where the value of a resource is determined by its value in use.

The 1969 system (the method used during the 1969–1976 period for grazing fee determination by the BLM and FS) includes three major elements. The first is the economic model and data collection survey used to establish the fair market value fee level of 1966. Second is the ten-year adjustment of grazing fees from previous levels to the fair market value level. Third, the procedure used to make annual adjustments in the fair market value. Nearly all of the controversy surrounding the grazing fees issue is with the adjustment factor. The procedure involves adjusting the 1966 base fee of $1.23 to current values by the Index of Private Land Lease Rates in the eleven Western States for dry land range.

A number of alternatives have been suggested by various groups to update or adjust the base fair market value fee of $1.23. Although each proposal is different they all bear the same basic concept, and that is adjustments should be made by changes in the price of output relative to changes in the price of inputs. The formula most often suggested was a Beef Price Index minus a Cost of Production Index. Other suggestions include arbitrary constraints on yearly adjustments or the use of moving averages.

A major concern at the external meetings was the quality of the data used to compute the Index on Private Land Lease Rates. There was also concern about the components of cost that were included in the Prices Paid Index (to be used as Cost of Production Index) as well as a redundancy between the Beef Price Index and the Prices Paid Index. The committee suggested that data on private land lease rates could be improved if it were collected on probability list frame sample that included only livestock operators instead of on a general Farm Report questionnaire. New questions were also suggested for the data collected. The Prices Paid Index could be improved by eliminating a number of cost items not relevant to western range livestock production. The redundancy in the Beef Price Index could be eliminated by excluding calves.

With a history of a market economy for all other products and resources used in agriculture, the obvious solution would be a competitive bidding system for the use of the public range. However, tenure arrangements, institutional goals, management restriction, and location of grazing lands has effectively eliminated the competitive requirement. Therefore less efficient administered pricing schemes must be developed. The task of the Technical Committee then became one of recommending the proper "proxi" for the competitive bid.

Adjusting grazing fees using the Index of Private Land Lease Rates (current method) may best be described as the comparative market approach. It is based on the premise that an individual will not pay more for the use of a resource than his next best alternative, or conversely, the owner of a resource should receive a value equivalent to that which could be realized from the next best alternative use of that resource. The committee felt that the index was a good indicator of long term adjustments taking place in western range livestock industry. It duplicates economic adjustments in the competitive sector, and is the only alternative suggested or discussed that incorporates measures of technical efficiency. Improvements made in the data collection process and discussed in the previous section should eliminate concern about the relevancy and accuracy of the data. However, the Technical Committee was concerned about the ability of the index to reflect short-run instabilities that result during periods of demand, supply and price disequilibrium. In the past this index has failed to account for short-run instabilities.

The combined index (Beef Price Index minus the Prices Paid Index) was rejected by the committee as the only adjustment factor in the grazing fee formula because it does not respond to long-run adjustments in resource use or efficiency, and would result in a declining real rent over time. However, it was felt that the combined index did reflect short-run instabilities in the value of the range resource.

Recognizing the strengths and the weakness of the current formula as well as the alternative formulas, the Technical Committee recommended the following formula for determining grazing fees levels on public lands:

$$\text{FMV Fee/AUM} = \$1.23\left(\frac{L+P}{100}\right)$$

L=The improved Index of Private Land Lease Rates.

P=The reconstructed Index of Beef Prices minus the Prices Paid Index (selected items only).

This formula is recommended in the light that it provides for a consistent and efficient method of pricing the public grazing resources. The long-run trend is based on the value of the alternative resource while at the same time accounting for short-run instabilities in either livestock prices or input prices. The committee has further recommended an improvement in the data collection procedures on the private land lease rates. Some modification was also suggested for the Prices Paid Index to make it more accurately reflect western range livestock operations.

NOVEMBER 15, 1976.

I. Introduction

The Technical Committee to Review Public Land Grazing Fees was formed by a Memorandum of July 12, 1976, in response to the request of Subcommittee on Environment and Land Resources, Committee on Interior and Insular Affairs, United States Senate, at the April 30, 1976 Committee Hearing on S. 3071. This report of the Technical Committee is transmitted to the Assistant Secretary for Conservation, Research and Education, U.S. Department of Agriculture; Assistant Secretary, Land and Water Resources, U.S. Department of the Interior; and Director of Agricultural Economics, U.S. Department of Agriculture.

The purpose of the review is to reconsider and examine the present 8-year-old formula for determining grazing fees in light of the criticism directed at it and the alternatives proposed.

The review by the Technical Committee:

A. Examines the present procedures for establishing grazing fees in light of recent criticism, and in light of its fulfillment of expectations in 1968–69.

B. Examines the several alternatives which have been proposed as replacement or modification for all or a portion of present procedures.

C. Identifies available or additional secondary data which might enhance the present or alternative procedures for determining fees.

The Analysis by the Technical Committee:

A. Determines the validity of various fee procedure proposals relative to the existing system and the existing Administration mandates.

B. Indicates combinations of data or procedures which are compatible with existing Administration mandates.

C. Indicates the ranking of the several proposals based on economic criteria.

D. Indicates useable data in modification of existing procedures.

E. Provides the basis for decision within the Administration on further action regarding fees.

II. Limit of Scope

The review was conducted within existing administration mandates that a fair market value fee must be collected (BOB, Circular No. A–25) and permit value would not be considered a valid cost factor for determining public land grazing fees. The collection of new primary data was not to be included in the study. However, the need for new studies and/or collection of primary data could be a conclusion of the review. The review and analysis was limited to a search of and use of available secondary data. New tabulation of existing data, new indexes, improved methods of collection of data for existing data series, or new use of existing data were considered.

External Consultations

In order for this review to be helpful in resolving, or reducing the controversy about grazing fees, it must serve to increase general understanding as well as meet technical criteria. The livestock industry, through the American National Cattlemen's Association and the Public Lands Council, was fully informed and involved in defining the nature and extent of this Review of Grazing Fees. The appropriate professionals of the Western universities were informed and involved. The environmental concerns were kept appraised through the National Wildlife Federation and the Wildlife Management Institute.

A meeting was held in Denver, Colorado on August 25, 1976. A second meeting was held in Washington, D.C. on September 20, 1976. At both meetings participants from the above listed interest groups presented their views on the public land grazing fee issue.

III. Criteria for Determining Fair Market Value of Public Grazing

An expression currently in vogue with younger people goes "whatever is fair", or a slightly different expression, "fair is fair". Like many slang expressions it does not have a precise dictionary definition, but its use connotation translates roughly "if you are satisfied, I'm satisfied". In short, "fair" expresses mutual satisfaction between parties involved. The key word is mutual. Fair also suggests justice or equity.

Economists have found no obvious way to determine what is "fair". Welfare comparisons would be relatively simple if it were possible to aggregate the utilities of individuals into a single utility function. However welfare comparisons of individual utilities are possible only in a very restricted sense. It is reasonable to postulate that social welfare transcends the more restricted notion of economic welfare, but for obvious reasons this analysis will be restricted to the latter.

Economic efficiency, often called Pareto optimality, states that the distribution of consumer goods and productive inputs are optimal if any feasible reallocation of goods or inputs causes a reduction in the satisfaction or output of any individual or firm. It can be shown that a perfectly competitive equilibrium satisfies these conditions, and thus perfect competition is a welfare ideal in this sense. Efficiency in the consuming and producing sectors implies further that the allocation of resources is pareto-optimal throughout the economy.[1]

A difficulty with the concept of economic efficiency or Pareto optimality as a welfare criteria is that it accepts the prevailing income distribution, i.e. return to resources. It is conceivable that the norm of perfect competition could lead to a condition in which the majority of individuals lived at subsistence or below. The analysis of welfare in terms of perfect competition leaves a considerable amount of indeterminancy in the solution. This indeterminancy results from the acceptance of the criteria that an increase in welfare was unambiguously defined as an increase in one individuals position without being accompanied by a deterioration in the position of another. This indeterminancy can only be removed by further value judgments.

An Economic Norm

The above discussion stresses the inability of economic analysis to handle a welfare criterion outside of the norm of economic efficiency. To do otherwise would require value judgments or ethical considerations outside the subject of economic analysis.

Few economists would claim that pure competition does or has ever existed in the United States economy. However, pure competition provides a logical starting place if one is to understand imperfect competition. Further it has been shown that a considerable amount of competition does exist, particularly in agriculture, and that the theory of pure competition gives valid answers to a great many economic problems.[2] Lastly the pure competition model provides a norm or ideal from which to appraise the workings of the economic system. In the latter sense it is often used for regulation of imperfectly structured sectors of the economy, such as public utilities, as well as many other public policy measures.

The term competition is used rather ambiguously in economic literature as well as in ordinary conversation. To many people the term commonly denotes rivalry. Whereas, when used along with the term pure or perfect, it takes on a different meaning. From the illustration and previous discussion competition implies mutual satisfaction, fair market value, and efficient resource allocation.

Resource Pricing Under Pure Competition

Pure competition in the resource market implies a number of conditions: One, no single firm controls enough of any given resource to be able to influence its price; two, no one supplier of a resource can place enough on the market to influence its price; and three, resources are mobile and can move between different uses and its prices are flexible.

How, then, are resources valued in production? Let us look at the simultaneously pricing and output of decisions involved in the use of a variable resource in the organization of production. Suppose two ranchers living in the same community, one with an excess of summer forage, the other badly in need of more summer forage. Further they know of each others problem. Rancher Tom, who needs more forage, goes to rancher Ray to see about renting some of his summer pasture.

"Ray", says Tom, "would you consider renting me some pasture for the summer, I need some grazing for one of my cows? I'd pay you $60 for the privilege."

Ray thinking to himself that the extra grass is only worth about $5 if he used it replies, "sure Tom glad to help out."

[1] For a more theoretical approach see: Henderson, J. M. and Quandt, R. E. Microeconomic Theory, McGraw-Hill Book Company, 1968, Chapter 7, pages 203–207.

[2] The assumptions of pure and perfect competition are given in most introductory texts in Economics and will not be elaborated on at this time.

Tom was willing to pay $60 for the privilege while Ray figured it was only worth $5 in its existing use. Both men were satisfied and felt that a "fair" deal had been reached.

The bargaining is not over yet though. Ray having rented up a unit of summer grazing found he didn't have such an excess of pasture anymore. Tom's problem on the other hand was not so urgent anymore, as he didn't find himself in the same need for summer pasture. An additional unit of summer pasture is now only worth $40 to Tom. Trading of grazing privilege for rent would continue between Tom and Ray until eventually the forage was of equal value to both ranchers. In other words, the last unit traded would have equal marginal value to both Tom and Ray in production. Thus, a mutually advantageous trading situation had been achieved, and maximum efficiency had been attained by both. No further trading of grazing privileges would be advantageous to either party. The equimarginal principle has been achieved.

In a free competitive market for forage, both Tom and Ray would trade grazing privileges for cash rent until a "fair" market value had been reached by both parties. In addition, an efficient allocation of resource would have resulted. Generalizing from this simple illustration it may be said that the principle of equimarginal value in use asserts that an efficient allocation of forage has been attained when no mutually advantageous exchanges are possible between any pair of claimants.

Theoretically, the manager combines his resources such that the marginal value product or each resource is equal to the marginal value product of all other resources used in production. The attempt is to combine all of his resources (e.g. land, labor, capital) in such a manner that the productive values of the last unit of each resource added are all equal. To maximize profit, the manager organizes resources such that the marginal value product of each resource is equal to each other and to the marginal revenue received from the last unit of output. This procedure is called the equimarginal principle and can be defined by a simple formula:

(1) $MVP_a = MVP_b = MVP_c = MC_x = MR_x = P_x$

where:
MVP_i=marginal value product of the ith resource in production.
MC_x=sum of the marginal value products of the ith resources combined to produce output x, or the equivalent of marginal costs of production of the $x_{(n)}$ output.
MR_x=marginal revenue of the last unit of output x.
P_x=market price of output x.

In a competitively structured society the organization of production is determined by the principle forces of supply and demand. This basic framework along with the decisions of the human agents involved and tempered by the intensities created by time, form, and place lead to a reasonably efficient duality of resource pricing and allocation. This has been particularly true in agriculture because of the absence of barriers to entry (except high capital requirements), homogenity of the product between firms of like output, agriculture's atomistic structure, and the relative mobility of resources both into and out of agriculture. A large number of research studies have verified the long-run efficiency of agriculture.

THE REAL WORLD

The discussion to this point has considered only the "ideal" resource pricing and allocation system. Economic efficiency and the assumptions of a competitive system were discussed, as well as reference to U.S. agriculture industry generally conforming to these standards. Theoretically agriculture should be efficiently organized, at least in the long-run adjustments period, and few people familiar with U.S. agricultural production would argue its resource and technological efficiency.

However, production levels, resource allocation and pricing has not been so efficient in the short-run adjustment period for many sectors in agriculture. Animal production, and in particular the primary production level for both beef and lamb have demonstrated relatively inefficient production adjustments in the short-run when measured against the neoclassical model which was described as the "ideal" system.

Twenty years ago Glen Johnson and others postulated the theory of fixed assets, where a fixed asset is defined as one for which the marginal value productivity of a resource in its present use neither justified acquisition of more of it, or its disposition. Acquisition cost is what a farm or ranch operator would have to pay in order to acquire more of a particular productive asset. Salvage value is what the operation would get for the asset if it were sold rather than used in production. Neoclassical theory, which defines the equimarginal principle, assumes that markets are such that a manager can purchase more of an asset if it were profitable and that he can dispose of unwanted quantities at the same price. This is tantamount to saying that a firm will continue to produce in the short-run as long as it realizes a return on its variable resources, or stated differently, a firm in the very short-run can survive with no return to its most fixed assets if its cash flow is adequate to cover variable expenses. However, the difference between the theory of fixed assets and neoclassical theory is that resources usually considered variable in production actually become fixed in their present use. For example, labor and capital are normally considered variable resources. However, at primary production levels these variable inputs actually become fixed to the firm because their alternative use outside of production can temporarily drop as far as zero. The value in use that would be expected to accrue to these resources is often used by managers to bid up the use value (returns) of resources that have continued to remain variable. In the theory of fixed assets Johnson has pinpointed the reason for extremely inelastic or irreversible supply functions during periods of decreasing marginal revenue.[3]

Let us examine some of the components of argiculture and in particular the primary production level of livestock that lead to this type of behavior during periods of decreasing product price levels.

First, the combination of resources used in the production process are not discrete, but a bundle or package of resources. Marginal changes in revenue may not cause an adjustment in output levels or resource use because the bundle of resources cannot easily be separated. For example, the physical amount of labor available to the operator may be fixed over a rather large range of production, but the use value of the labor is variable. The balance between summer and winter forage may be unalterable at least in the short-run. If a shortage of summer pasture should occur the firm may be forced to bid up the value of this resource while simultaneously taking smaller returns on the remaining resources in the bundle, even in the face of decreasing marginal revenue for their product.

Second, variable resources become fixed because of the length of the production process. The primary reason for this is the time required for the biological process for plant and animal production. It may take two or more years from the time a market stimulus is received at the primary production level until actual output adjustments can be achieved. Time requirements for an increase in production can take three years or more for obvious reasons. The time aspects alone could cause inelastic short-run adjustment in resource use and output levels.

Third, the demand curve faced by the firm is perfectly elastic while that of the industry is inelastic. Individual firms fail to adjust output levels in the short-run, because of the atomistic structure of the industry.

Fourth, the duality aspect of the price system may work imperfectly. The role of price as a mechanism of trade is generally regarded as extremely efficient; However, the role of price as an organizer of production generally lacks the same performance standard. The problem may be that the human agent may be unable to bridge the gap from present product prices to expected price levels in the future. This lack of adjustment is

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[3]The concept of asset fixity is well documented in the following list of publications:

a. The Overproduction Trap In U.S. Agriculture, Glen L. Johnson and C. Leroy Quance, Resources for the Future, John Hopkin Press, 1972.

b. Glen L. Johnson and Lowell S. Hardin, "Economics of Forage Evaluation", Station Bulletin 623 (Lafayette: Purdue Univ. Agricultural Exp. Station, Apr 55).

c. Clark Edwards, "Resource fixity and Farm Organization"; Journal of Farm Economics, 41, Nov 1959).

d. G. L. Johnson, "Supply Function—Some Facts and Notions", Agriculture Adjustment Problems in a Growing Economy, (Ames, Iowa State College Press, 1958) p. 78.

closely related to length of the production process.

In summary, this discussion has pointed out some of the reasons the competitive or "ideal" system leads to short-run imperfections regarding resource valuation at the primary production levels of agriculture. The principle reason cited was the concept of the fixity of assets. While the competitive norm accurately values resources in the long-run, it has some shortcomings in the short-run adjustment period. Short-run instabilities have a significant effect on the value of resources used in production. In the case of administered prices, failure to recognize potential imperfections in the price norm results in windfall gains and losses. During periods of increasing marginal revenue the government would fail to receive full fair market value for its range resources. Conversely during periods of decreasing marginal revenues the government may charge in excess of fair market value for the range resource. The equimarginal principle states that the value of a resource is determined by its value in use.

IV. Conditions, Assumptions and Issues

The Committee uses the concept of an animal-unit-month (AUM) throughout the report. An AUM is the amount of forage consumed by a cow-calf unit during one month. Other livestock are converted to the AUM equivalent. However, the concept is extended to recognize that with the forage the consuming animal unit also has use of a habitat, a place to live. This habitat includes the forage, watering facilities, fencing and other improvements necessary to make the range usable by livestock and to provide for control of the livestock.

INSTITUTIONAL GOALS

It is the objective of the Forest Service and BLM to contribute to the economic stability of individual ranch units to the fullest extent possible and consistent with protection of the resource and its long term productivity. This has resulted in establishment of policies which allocated grazing privileges based on:

A. Prior use;

B. Dependency, or the need for forage to round out a yearlong livestock enterprise;

C. Commensurability, the ability to carry livestock on home ranch lands during the time they were not on public lands; and

D. 10-year, renewable grazing privileges.

The effect of these actions is to maintain long term availability and use of public land associated with a given ranch unit. These provisions allow the operator to plan long-term enterprise development and investment.

COMMUNITY STABILITY

Grazing of livestock, under permit, on the Public Lands has a substantial impact on the rural communities associated with that grazing. The greater the percentage of land held in Federal ownership, the more the area or communities' basic economic activity relies on use of Federal land, and the greater the impact of Federal policies on the total economic activity and stability of those rural communities.

CONSERVATION AND ECONOMIC EFFICIENCY OF RESOURCE USE

Direct involvement in the development and long term use of land resources is generally considered to provide incentives for protection and economic development of the resource. Essentially, security of tenure provides the ability to plan ahead for a reasonable length of time with some degree of certainty.

RELATIONSHIP OF FEES TO TOTAL COMPLEX OF USES OF PUBLIC LANDS

Commercial enterprises using the public lands all pay fees which are intended to be the equivalent of fair market value. The only users exempt from payment of fair market value are those involved in individual or group activities primarily for personal enjoyment.

ADJUSTMENTS IN COST STRUCTURE NEEDED TO REFLECT GOVERNMENT REQUIREMENTS AND ENVIRONMENTAL ADJUSTMENT

It is claimed that there has been relative changes in the FS/BLM non-fee grazing cost over the private land leasing costs over the past eight years. The three most cited examples of increased cost to the rancher grazing on public lands are:

(1) Increased animal (sheep) losses because of restricted coyote control on public lands,

(2) Agency requirements for increased rancher participation in structure maintenance, and

(3) Agency requirement for increased participation of ranchers in grazing management practices.

If these claims were in fact true, then the next logical step would be to determine the magnitude of the cost change and make the corresponding corrections in the non-fee grazing cost which would increase combined federal grazing cost and reduce the base fair market value of $1.23 per AUM.

The fundamental basis for the claim of increase sheep losses due to predatation is the restrictions placed on some coyote control practices on public lands. While some individual rancher losses may have increased, there are no substantive data to quantify the claim. Also, the non-fee public grazing costs are weighted by corresponding AUM's for sheep and cattle and any increase in sheep cost would have liimted effect on the weighted average.

The Federal agency policy for rancher participation in maintenance of livestock facilities has not changed. There has however been an increase in the application of the maintenance policy in some range areas that previously were not fully affected by maintenance requirements. In recent years it has been BLM policy not to encourage the rancher to construct facilities on public lands because of possible multiple use management conflicts. Again, there are no quantifying data to support the contention that relative changes have taken place in the over-all project maintenance and depreciation costs between private and Federal grazing lands.

The third item relates to increased emphasis placed on intensive grazing management of rangelands and usually associated with some "system" of grazing control. These grazing systems or management plans usually require the movement of livestock several times during the grazing season between pastures to insure that multiple use objectives are met and the physiological needs of the desirable vegetation are taken care of. While some increased operating cost may be incurred there are direct compensating benefits to the rancher of increased stocking rate stability, decreased livestock conflicts with wildlife habitat requirements, improved range conditions and usually increased animal production. Increasing numbers of ranchers are leading the way in intensifying grazing management efforts on private lands so the condition is not unique to public lands. The costs and benefits to the public land user resulting from intensive management can not be identified in this review.

V. Existing and Suggested Alternatives For Fee Determination

The 1969 fee system (the current method used for grazing fee determination by the BLM and the FS) includes three major elements. The first is the economic model and data collection survey used to establish the fair market value fee level of 1966. Second is the ten year adjustment of grazing fees from previous levels to the fair market value level. Third, the procedure used to make annual adjustments in the fair market value.

THE ECONOMIC MODEL AND GRAZING SURVEY OF 1966

The economic model was designed to measure the value of grazing on public lands through a detailed comparison of grazing costs on public and privately owned leased lands. The model is based on the premise that the total on-the-range costs of grazing on public lands and on private owned leased lands should be equal and would represent a means for determining fair market value of public grazing. The public grazing fee would be the amount necessary to equalize the private land lease plus the on-range-cost of using the public lands.[4] In other words the public grazing fee would equal the private lease rate minus the difference in costs incurred in using public range versus private range.

The economic model, because it required only data from operating livestock

[4] Specific items compared for differences in the cost of grazing on public lands compared to private lands include: Lost animals, Association fee, veterinary, moving livestock to and from allotment, herding, salt and feed, personal travel to and from allotment, water, horse, fence maintenance, water maintenance, development, depreciation, other costs, and private lease rate.

production units eliminated most of the influence of non-livestock grazing related values, and only measured the level of total costs operators were willing to incur in leasing privately owned land for grazing purposes. The model specifically measures the different and varying requirements placed on the leasee or permittee by both the private and Government landowner. The model measured the value of contributions required by either landowner, including the requirement for construction, repair, replacement and maintenance of permanent improvements.

The data for use in the model were collected by the Statistical Reporting Service in 1966. Ten thousand (10,000) individuals were interviewed and over 14,000 questionnaires were completed. Interviewees included Forest Service and BLM grazing permittees, ranchers who leased private land, and lending institutions.

The data were analyzed by a Technical Committee composed of representatives of the Statistical Reporting Service, Economic Research Service, Forest Service, Bureau of Land Management, and the Bureau of the Budget (now Office of Management and Budget). The Technical Committee came to the following conclusions: first, the data did not provide a basis for differential feees between Forest Service and BLM. The data could be combined and single fee established for BLM and Forest Service grazing; two, the data did not provide a basis for establishing separate fees for cattle and sheep; three, the data and analysis provided a basis for a public land grazing fee of $1.23 per animal unit month.

The conclusion of the Technical Committee provided the basis for the establishment of $1.23 per AUM as the fair market value grazing fee level for 1966 on public lands in the West.

Ten Year Adjustment Period

In order to minimize the impact of adjusting from BLM's 33 cent fee in 1966, and Forest Service's average fee of 51 cents, a 10-year schedule was developed for adjusting to the $1.23 fee level. By spreading the increase in fees over a period of time, the initial impact of the fee increase on the permittees would be minimized and allow a normal adjustment to this increase. The Forest Service starting in 1969 would add 7.2 cents to the fee charged in 1966 for each of the next ten years. BLM would add nine cents to the fee charged in 1966 for each of the next ten years. The result would be that by 1978 both FS and BLM would be at the 1966 fair market value figure of $1.23.

Adjustments in Fair Market Value

Adjustments to the fair market value level of $1.23/AUM in 1966 were necessary to reflect changes overtime in the profitability of range livestock production and prevent future inequities between federal grazing fees and the value of the range forage for grazing use. The base fee was adjusted annually with an index of private grazing land lease rates for the 11 Western states. The private grazing land lease rate is the charge per head per month for pasturing cattle on privately owned lands. The actual values are converted to an index (1964–68=100) in order to measure the rate of change in this price series. The index is then applied to the 1966 base of $1.23.

The private land-lease rate was selected for the adjustment factor because: one, it was an existing and available data series; and two, it represented changes in the economic value of grazing use. It is representative of the economic value of grazing because it is established by the amounts livestock producers are willing to offer for the use of available private grazing lands. Given these conditions, it is expected that these offers represent the value of grazing to the livestock producers.[5]

Alternative Fee Systems

A number of alternatives have been suggested by various groups to update or adjust the base fair market value fee of $1.23. Although each proposal is different they all have the same basic concept. This concept is that adjustments in the base value ($1.23) should be related to changes in the price of the product and to changes in the price of inputs. The procedure intends that when the change in value (price) of products (beef cattle) is larger than changes in price of inputs (cost of production), then fees should increase. If the change in costs exceeds the change in product value, then the fee should decrease.

(BPI–PPI+100=CI)

This formula would replace the private land-lease rate formula for the necessary update adjustments for the 1966 base, and for lack of a better name is called the Combined Index. In this formula BPI is an index of the weighted average annual prices for beef cattle, excluding calves, for the 11 Western States. The base would be 1964–68=100. The Prices Paid Index (PPI) is an index of prices paid by farmers for commodities and srevices, interest, taxes and farm wages as collected and published by the Statistical Reporting Service, in "Agricultural Prices." The index would be adjusted to the base of 1964–68=100.

Another suggested alternative using the Combined Index as a replacement for the private land-lease rate would be that the data would represent a simple moving average. This would have the effect of reducing the impact of large yearly variations in the level of grazing fees.

A third suggested alternative would be to add the combined index to the currently used index of private land lease rates. In this formula, when divided by two, fifty percent of the change in the lease fair market value ($1.23) would result from the private land-lease rate index and fifty percent from the combined index.

[5] See Appendix Table 1 and 2 for charges resulting from the 1969 Fee System and the Source of Fee Increases.

Santini Formula

This set of alternatives uses the combined index, but also replaces the $1.23 base for fair market value in 1966 with other value(s) for 1975. The Santini formula would establish two groups of grazing lands based on carrying capacity of the public lands. The constant or base figure for Group I lands is $1.70 and for Group II lands $1.40 per animal unit month (AUM).

A version of the above, called the Modified Santini Formula, would make adjustments using the combined index, but the base would be $1.51, the average grazing fee charged in 1976 by BLM and FS.

The Hansen formula, which was contained in S. 3071, is the same as the Santini Formula except the Beef Price Index would be computed using prices for the 48 states and the PPI and the BPI would be a moving three-year simple average.

Economic Relief Formula

The economic relief formula (so named for lack of an alternative) uses the current formula based on $1.23 and the private land-lease rate index, with a separate analysis of the PPI and BPI or some similar indices, to trigger needed adjustments in the current fee due to stress economic condtions as indicated by the BPI and PPI analysis.

A number of other alternatives have been suggested to limit the impact of large changes in economic conditions. One suggestion was to limit the amount of increase that could occur in any period by a fixed percentage. Another suggestion was to incorporate a rolling three-year average into the existing formula.

Discussion

Most all of the alternatives proposed have merit, and suggest the interest and responsibility of users of and those interested in the use of the public lands. All of the alternatives proposed including the current system have advantages and disadvantages. In other words, there is no perfect lease arrangement, but only better or worse arrangements. This may explain the large variability of lease arrangements in effect around the country between landlord and leasee. Logic and reasonableness does, however, provide a basis for reducing, if not eliminating, conflict between interested parties. The task of this technical committee is to consider the alternatives in light of the economic criteria and recommend a method for determining a fair market value.

VII. Data Sources

A primary objective of this committee was to identify existing data sources, and/or refinements to existing data sources, and/or additional data that might be collected to enhance the present or alternative procedures for determining grazing fees.

A major concern at the external group meetings was the quality of the data

that are used to compute the index on private land lease rates. There was also concern about the components of cost that were included in the prices paid index, as well as a possible redundancy in the beef price index and the prices paid index.

PRIVATE LAND LEASE RATES

The Statistical Reporting Service, USDA currently obtains information on the average rate for pasturing cattle on non-irrigated privately owned land on a per head per month basis. The survey is a nonprobability survey; data is collected in March each year on a general Farm Report questionnaire. The table below indicates the number of responses to the question on pasturing cattle on privately owned non-irrigated pasture land for 11 Western states for the years 1967–75.

TABLE I.—*Number of responses by State by year to question on pasturing cattle on privately owned nonirrigated pasture land*

State	Year								
	1967	1968	1969	1970	1971	1972	1973	1974	1975
Montana	242	148	196	229	151	168	180	161	159
Idaho	123	73	104	88	85	89	69	57	77
Wyoming	72	56	50	44	45	29	28	81	64
Colorado	219	177			229	213	242	299	218
New Mexico	76	65	34	30	30	36	19	31	39
Arizona	17	14	17	15	10	15	10	7	4
Utah	80	71	85	104	95	129	84	72	60
Nevada		19		17	11	8	8	8	9
Washington	176	132	132	128	115	81	104	66	97
Oregon	198	142	158	143	72	72	120	67	89
California	138	95	98	132	148	130	125	63	119
Total	1,351	992	874	930	1,000	961	1,019	821	965

The SRS Farm Report Questionnaire is mailed to a non-probability general purpose list, including grain farmers, dairy farmers, fruit farmers, etc. In the 11 Western States, approximately 12,500 questionnaires are mailed in March. The question on pasturing cattle on privately owned non-irrigated land is summarized and provided to the Economic Research Service, USDA for analysis and publication. Forest Service, USDA and Bureau of Land Management, U.S. Department of Interior, use these data in adjusting the range forage index each year based on an average head-month rental of $3.65 for the 1964–68 period equal to 100. The adjusted RFI for each year is the 11-State average head-month rental for that year divided by the $3.65 AUM average.

DATA IMPROVEMENT

The Statistical Reporting Service currently has operational two mid-year probability surveys in the 11 Western States. One of the mid-year surveys is a cattle multiple frame survey that utilizes a list frame with a non-response follow-up. The second probability survey, known as the June Enumerative Survey, consists of land areas and identifies operations not covered by the list frame. About 10,800 multiple frame questionnaires were tabulated in nine Western States in 1975. In addition, the June Enumerative Survey, a probability area frame survey, which is conducted in the other two Western States, had approximately 1,700 survey questionnaires completed last year. If it is desirable to have the adjustment factor for the Range Fee Index to be on a probability basis, the vehicle is available to provide this type information. Questions that would be added to the mid-year survey are as follows:

All Non-Irrigated Grazing or Pasture Lands.

1. Average rate for pasturing cattle on privately owned land in this area this year per head per month _____

2. Do you personally rent privately owned non-irrigated pasture on:

(a) A per head per month basis? _____

(b) A per acre bases? _____

3. If yes, how many head of cattle are you pasturing this year on the privately owned non-irrigated pasture? _____

4. How many days will you have these cattle on the rented pasture? _____

5. Total rent paid for pasturing these cattle on privately owned pasture this year _____

The cost of adding these questions to the two surveys would be $20,000.

INDEX OF PRICES PAID BY FARMERS

The Index of Prices Paid by Farmers measures the average change in prices paid for commodities and services bought by farm families.

The index is made up of five major components. In terms of farm expenditures, the two most important components are the index of prices paid for commodities used in farm production and the index of prices paid for commodities used in family living. These two indexes comprise the Index of Prices Paid by Farmers for Goods and Services. The remaining three components of the Index are: (1) Interest charges per acre on mortgage indebtedness secured by farm real estate; (2) Taxes payable per acre on farm real estate; and (3) Wage rates paid to hired farm labor.

Two major indexes within the Prices Paid by Farmers Index are stratified further into 18 group indexes. The Farm Production Index is divided into 12 group indexes—feed, feeder livestock, seed, fertilizer, agricultural chemicals, fuels and energy, farm and motor supplies, autos and trucks, tractors and self-propelled machinery, other machinery, building and fencing materials, and farm services and cash rent. The Family Living Index is divided into six group indexes—food, clothing, housing, autos and auto supplies, medical and health, and education, recreation, and other.

As of June 15, 1976, the farm production component of the Index included 169 different commodity price series; the family living component 152 items—for a total of 321. Prices for 25 items are used in both family living and production indexes leaving a net of 296 separate price series. In the Family Living Index the medical and health and education, recreation, and other indexes are based on Consumer Price Indexes from the Bureau of Labor Statistics, and are excluded from the commodity price series count.

Price data used in the computation of the various indexes are collected largely by mail from independent and chain stores serving rural areas. Separate commodity price estimates are made for independent and for chain stores as of the 15th of the quarterly month. These separate price estimates are weighted together to obtain averages of prices paid by farmers for most family living and farm production items. In other months, prices are estimated only for chain stores which provide the basis for current index computations for the interquarterly months.

The U.S. commodity prices are computed by weighting State estimates of average prices by the estimated quantities of products purchased by farmers in each State. U.S. average prices are then combined into the group indexes, using as weights the estimated quantities of the individual commodities purchased by farmers based on a 1971–73 surveys of farmers' expenditures. Official data of the Agricultural Research Service and the Agricultural Marketing Service are also used to supplement the survey indications.

Group indexes are combined into their respective family living and production indexes, using percentage weights representing the estimated proportion of expenditures of farmers for each commodity group. These also were derived primarily from the 1971–73 Expenditure Surveys. The family living and production indexes are in turn combined into the all-commodity index of prices paid, using weights representing the proportionate expenditures for these two segments. In like manner, all commodities, interest, tax, and wage rate components are weighted, on the basis of relative expenditures, for the index of Prices Paid by Farmers.

DATA REFINEMENT

If certain components of the index of prices paid were needed to comprise a new index to reflect cost of production of cattle producers in the United States, the Statistical Reporting Service could provide such an index. Possible components to use in indicating cost of cattle production from the Index of Prices Paid are motor supplies, motor vehicles, farm machinery, farm supplies, building and fencing materials, interest per acre and wage rates. Weights could be derived from the 1975 Meat Animals Cost of Production Survey conducted by SRS for the Economic Research Service. Data from this survey are currently being summar-

ized by ERS and should be available for analysis by January 1, 1977. The new index could then be used in a combined index formula. One such formula would be to subtract the Prices Paid Index from a Beef Price Index. The resulting combined index multiplied by a base fee would result in the annual grazing fee. This, or some derivative, to determine an annual grazing fee, is possible to compute if such a formula were used.

BEEF CATTLE PRICE

Monthly, the Statistical Reporting Service publishes an all beef cattle price for all States and for the U.S. This price is comprised of a weighted average of (1) steer and heifer prices and (2) slaughter cow prices. An allowance, if necessary, is made for slaughter bulls. Data used in making these commodity estimates includes prices from market news sources, tabulated auction sales data and survey data from individual farmers.

State data are then weighted by historic beef cattle marketings, by month, for each State to establish the monthly beef cattle price for the U.S.

The Statistical Reporting Service can provide the annual average price for beef cattle and lambs for any grouping of States. Final State prices are weighted by marketing data. Groupings of 11 States and 15 States have been made available to Forest Service and BLM for many years, for administrative use only. Final annual average prices by States are published in the February issue of *Agricultural Prices*. The April issue contains U.S. averages.

VII. EVALUATION OF VARIOUS FEE FORMULAS

With a history of a market economy for all other products and resources used in agriculture, the obvious solution to the problem of pricing public grazing would be to open it up for competitive bidding. After all competitive bidding would extract the full fair market value of public range for the public coffers. It would allow all citizens to compete for the use of the resource, and at the same time keep our public ranges producing beef and mutton. In addition, resource use and product output would be at its marginal value product level, and the public good would almost certainly be served by the resultant competitive conditions.

However, a competitive bidding system would presume a relatively free and competitive market, a condition that does not exist for many users and potential users of public grazing on BLM and National Forests lands. Institutional goals, tenure arrangements, legislative requirements and management restrictions of the National Forest System and Taylor Grazing Districts effectively eliminate a competitive environment. The location of grazing allotments, property boundaries, terrain, and water development further reduce the competitive environment. It has been estimated that as much as twenty percent of BLM land is "captive" in that it would be difficult if not impossible for any other livestock operator to use certain public land tracts. Other lands are grazed in common by a number of livestock operators and should not be broken up into separate allotments.

Thus, the competitive bidding system appears infeasible as the necessary conditions for an operational system does not exist, less efficient administered pricing schemes must be considered. In each of these pricing methods the objective is to simulate the competitive bid by employing "proxi" variables derived from the competitive environment of the livestock industry.

It is the task of this Technical Committee to attempt to recommend the proper "proxi" for the competitive bid. Attention will be directed to the Index of Private Land Lease Rates and the Combined Index (BPI–PPI). The committee will also comment on the two tier fee system proposed in S. 3071.

INDEX OF PRIVATE LAND LEASED RATES

This method may be best described as the comparative market approach. It is based on the premise that an individual will not pay more for the use of a resource than his next best alternative, or conversely, the owner of a resource should receive a value equivalent to that which could be realized from the next best alternative use of that resource. Using this premise the public grazing fee should equal the private grazing rate, less the difference in the cost of using public range over private range. In the grazing fee formula, the absolute level is ignored and only the rate of change over time is used to update the base fee of $1.23 for 1966.

The use of the comparative market approach has considerable merit. First, its value is derived from the competitive environment. Second, it theoretically measures changes in efficiency of range resource use over time. Third, it should give a close estimation of the fair market value that would be obtained under a competitive bidding system. Thus, it would also fulfill the criteria of the "ideal" pricing system. Fourth, it reflects changes in the level of economic parameters such as the inflation rate, purchasing power of the dollar, and the value of farm real estate.

Critics of the Index of Private Land Lease Rate point out that land prices and net rents have a strong functional relationship. They argue that land prices on a per acre basis have increased six fold during the last 30 years, while net farm income per acre has shown no distinct trend during the same period. This behavior is hypothesised to be related to pressure for farm and ranch enlargement. Because land is a limiting resource an increasing portion of net farm income is being capitalized into the land resource. Active farmers and ranchers attribute near zero value to their labor, management, and some of their invested capital in order to pay for land, thus violating the equimartinal principal for resource valuation.

Another argument against the Index of Private Land Lease Rates is directed at the accuracy of the data. It is argued that the data represent non-livestock uses. Others point out that typical leases in the private sector are not negotiated on a head month basis, and that those responding to the survey question are not making proper transition from the actual existing lease to the head month lease basis.

The position of the Technical Committee is that the Index of Private Land Rates is a good indicator of long term adjustments taking place in western range livestock industry. It duplicates economic adjustments in the competitive sector, and is the only alternative suggested or discussed that incorporates measures of technical efficiency. Improvements made in the data collection process and discussed in the previous section should eliminate concern about the relevancy and accuracy of the data. However, the Technical Committee is concerned about the ability of the Index to reflect short-run instabilities that result during periods of disequilibrium. In the past the Index has failed to account for short-run adjustments in resource valuation.

COMBINED INDEX

This formula consists of the Index of Beef Prices and the Prices Paid Index. The formula was suggested by the American National Cattlemens Association (ANCA) and is usually referred to as the parity formula or the "ability to pay" formula. Several slightly differing versions have been offered but the Combined Index has been the nucleus of all of the proposals.

The goal of parity in the past was generally ridiculed by economists as not meaningful. But parity as defined in terms of equal resource returns should be close to their hearts after all the concept of "equal resource returns" is a primary condition defining the most efficient allocation of resources in the competitive market. When all factors are employed so that marginal returns to resources are equated within the industry and between agriculture and the nonfarm economy, maximum output of goods and services are obtained.

A second source of support for the combined index is related to economic stability. Returns to resources in the long-run have demonstrated an efficient agriculture and in particular beef cattle. However the cattle industry has shown a considerable degree of instability in the short-run return to resources. The instability results in windfall gains and losses to both the government and the ranchers alike.

Critics of the combined index insist that the formula is not directly measured in the competitive market, and consequently contains no measures of long run efficiency in resource use. It is based on the premise of constant purchasing power or constant relative income and does not allow for resource adjustment. A second part of the above argument is the cost of alternative or substitute inputs are not considered and thus it is not a fair proxi for the competitive market.

The formula has also been criticized for containing elements in the indices which are not used in western range live-

stock production (e.g. seed, fertilizer, and etc.). It was pointed out in the previous section on Data Sources that these elements could be deleted from the prices paid index and proper weights be reassigned from the cost of production study currently in progress by thhe Economic Research Service and the Statistical Reporting Service.

The third major criticism relates to the fact that the index does not respond to the inflation rate or the value of the purchasing power of the dollar. If the combined index were used as the only method of adjusting grazing fees, the public would receive a declining real rent in the long-run. In effect the rent that the rancher paid for the use of the resource would only be at "fair market value" in the base period.

The Technical Committee noted the shortcomings as well as the advantages of the combined index. The index was recognized as a poor indicator of long-run adjustments because of the behavioral nature of indices measuring differing sectors of the supply-demand model simultaneously. For this reason the committee rejected the use of the combined index as the sole adjustment factor in any grazing fee formula. However, the committee also recognized the inability of the index of private land lease rates to measure short-run instabilities particularly in an environment where the value of value of the resource (public grazing) is a derived demand from the product it produces (beef and lamb). Therefore the committee concluded that the range fee formula should include factors that measure changes in the value of the range resource in both the long-run and the short-run.

THE TWO TIER SYSTEM, S. 3071

A procedure requiring the establishment of two levels of grazing fees based on the number of acres required for one animal unit month has been proposed by the Public Land Council and was outlined in S. 3071.

The variable fee hypothesis suggests that the value of native rangelands for livestock grazing is directly related to only one element of the lands, the density of desirable vegetation. If rangelands had no other characteristics and ranching operations were all the same, this hypothesis might be a reasonable assumption. However, these Federal rangelands have many features and conditions, some constant and some changeable, that affect their economic value to the individual stockman. Forage quantity, as a component of grazing value, varies in terms of quality from place to place and from season to season. These variations do not directly change the relative dollar value of the grazing since availability and cost of alternative feed sources for each individual rancher also impact on the economic value of the native forage to the livestock producer.

As an example of conditions that do not support the variable fee argument consider: (1) Grazing capacity allowance for livestock may be reduced to accommodate wildlife and wild horse habitat needs and therefore would not relate directly to forage quality or land productivity. (2) Intraallotment differences in forage production and grazing conditions are just as variable as interallotment differences. (3) Livestock water may be the limiting factor on some rangelands and not forage quantity and (4) Winter ranges (usually of low productivity) may have greater economic value to the stockman than summer ranges (usually of higher productivity) because the alternative is to feed expensive hay.

In setting up the 1966 Western Wide Grazing Fee Study, there was then as now a strong belief by some that a variof one or more of the qualitative variables such as grazing capacity, season of use, geographic area, or vegetative type. One of the conclusions of the study was that there was no basis for recommending differential base fees among ranching areas.[6] An independent analyses by the BLM during 1967 identified that there are larger user-cost differences between ranchers within any categorical grouping than between the groups.[7] In essence, there was no statistical evidence in the study to support a variable fee. The Arthur D. Little Company, Inc., made an independent statistical analysis of the BLM and private grazing survey data. The results of this independent analysis supported the previous findings.[8]

The suggestion that an inequity is created when the same grazing fee is charged for grazing on high productivity land as for low productivity land is misleading because the unit of measurement for public land grazing is an animal unit month and not an acre of land. Also, there is no analysis available that the committee is aware of to support using 11 acres per AUM as the proper economic value point for dividing rangeland values for livestock grazing. The definition appears to be arbitrary and without foundation for establishing fees on public lands.

Under existing law and Executive policy a variable fee system is permitted but is not required unless specific inequities can be documented. Most of the questions and issues regarding grazing fees are related to managerial judgments and general economic factors more fundamental than public land user charges. Basically, the AUM and hence its general market value are the same from area to area since the grazing requirements of the animals are met and the yearly production cycle of the ranches are maintained. To recognize and differentiate public land grazing fees on the basis of detailed individual differences would require individual negotiation of fees with each of the 25,000 individuals using public lands.

[6] Housemen, Earl E., et al., "Special Report on Grazing Fee Study", USDA, Statistical Reporting Service, Oct. 24, 1968.

[7] Progress Report on Grazing Fee Study as of August 1, 1967, USDI, Bureau of Land Management.

[8] Arthur D. Little, Inc., "An Analysis of Western Livestock Grazing Costs, A Report to USDI," June 1967, Case No. 69463.

VIII. RECOMMENDATIONS

Establishing a grazing fee formula which is completely acceptable to the various management agencies and the users of Public Lands is a difficult task. It must accurately reflect the value of the resource and still take into account institutional restrictions and goals. Given the inability of economics as a discipline to aggregate individual utilities onto a single function, the next best alternative appears to be a "proxi" for the norm of economic efficiency. In the absence of a better criteria this value judgment will have to be acceptable.

Because a competitive environment does not exist, and can not exist given the current institutional constraints and goals, the members of the Technical Committee recommend the following formula as a proxi for the competitive market bid for grazing on an AUM basis:

$$FMV = A\left(\frac{L+P}{100}\right)$$

FMV—Fair Market Value for public grazing.

A—$1.23 base established from 1966 survey.

L*—Index of Private Land Lease Rates.

P**—Combined Index (BPI–PPI).

*The data for construction of this index should come from the probability based combined list frame sample described in Section V.

**BPI is a weighted index of average annual beef cattle prices less calves in the 11 Western States. PPI is an index of prices paid for inputs and would include only the seven items listed in Section V, and weighted by the Cost of Production Survey.

This formula is recommended as it provides for a consistent and efficient method of pricing the public grazing resources. The formula will reflect long-run trends in grazing values while at the same time accounting for short-run instabilities in either livestock prices or input prices. The committee has further recommended an improvement in the data collection procedures on the private land lease rates. Some modification was also suggested for the prices paid index to make it more accurately reflect western range livestock operation.

The Technical Committee has recommended the above grazing fee formula on its logical consistency. The data recommended for construction of the indices are not available for testing at this time. However it was assumed that the values for private land lease rates to be collected using the recommended improvements would be identical to the current data methods because the values will come from the same universe. Therefore the value of $3.65 from the base period of 1964–68 would continue to be the proper base for the index of private land lease rates.

It is further recommended that the mechanics of the formula be developed in detail by a work group staffed by members of the Forest Service and the Bureau of Land Management. The committee believes an upper limit of 25 percent could be imposed in the event of changes in economic conditions that

would force a sudden increase in grazing fees. Other mechanics are at the discretion of the management agencies.

TABLE 2.—*1969 fee system—Fair market value and fees actually charged*

[In dollars per AUM]

Year	Fair market value	National forest fees		BLM fee
		Average	High and low	
1966	1.23	0.51	1.64-0.19	0.33
1968		.56	1.80-.21	.33
1969	1.25	.60	1.25-.31	.44
1970	1.29	.60	1.25-.31	.44
1971	1.36	.78	1.36-.53	.64
1972	1.37	.80	1.37-.55	.66
1973	1.41	.91	1.41-.68	.78
1974	1.54	1.11	1.54-.92	1.00
1975	1.96	1.11	1.54-.92	1.00
1976	1.94	1.60	1.94-1.45	1.51

TABLE 3.—*Source of increase in fees*

[In dollars per AUM]

	National forests to		BLM to	
	1976	1980	1976	1980
1966 base value	0.51	0.51	0.33	0.33
Sum of incremental adjustments	[1].38	.72	[2].47	.90
Sum of adjustments by private grazing land lease rate index	.71		.71	
Total fee	1.60	1.23	1.51	1.23

[1] 4 at 0.072 plus 1 at 0.09 equal 0.38.
[2] 4 at 0.09 plus 1 at 0.11 equal 0.47.

[FR Doc.77-3310 Filed 2-3-77;8:45 am]

federal register

FRIDAY, FEBRUARY 4, 1977

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

COLOR ADDITIVES

Provisional Regulations; Postponement of Closing Dates

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 76N-0366]

PART 8—COLOR ADDITIVES

Subpart—Provisional Regulations

POSTPONEMENT OF CLOSING DATES

The Food and Drug Administration (FDA) is postponing the closing dates for the use of 52 provisionally listed color additives. The postponements are conditioned on the undertaking of appropriate scientific investigations and the submission of data to FDA on a prescribed schedule. This order is effective January 31, 1977.

The Commissioner of Food and Drugs proposed, in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860), to postpone the closing dates for the use of certain provisionally listed color additives beyond December 31, 1976, conditioned on the undertaking of appropriate scientific investigations and the submission of data to FDA. The Commissioner proposed to prescribe the required scientific investigations and other procedures for these provisionally listed color additives in new § 8.505 (21 CFR 8.505). The proposal was part of the Commissioner's publicly stated commitment, published in the FEDERAL REGISTER of January 5, 1976 (41 FR 754), to make final determinations about "permanent" listing on as many of the provisionally listed colors as possible and to take steps to resolve finally the status of each of the provisionally listed color additives.

In response to the proposal the Commissioner received 104 comments; they came from consumers, a consumer group, growers and producers of cherries, trade associations, and manufacturers and users of color additives. The comments received and the Commissioner's responses to them are summarized below.

1. Several comments from consumers and a consumer group objected to continued provisional listing of any color additive on the ground that manufacturers and users have had sufficient time since enactment of the Color Additive Amendments of 1960 to establish the safety of all color additives. The comments said that any color additive that has not been proved safe by now should be removed from the provisional list and its use should be prohibited.

The Commissioner advises that various factors have prevented quick decisions about "permanent" listing of certain provisionally listed colors. Three factors—the time needed to do studies on the additives, a legal challenge to FDA authority over cosmetic ingredients, and changing scientific standards for the evaluation of food and color additives—account largely for the delay. These factors are further discussed below.

The regulation below results from the Commissioner's commitment to "close the books" on the provisionally listed color additives. The regulation prescribes both a schedule for the prompt resolution of the status of each provisionally listed color additive and procedures to ensure that the schedule will be followed.

The process of resolving the status of each provisionally listed color additive began with a comprehensive review by FDA scientists of all available data on each provisionally listed color additive. The review was conducted to determine whether the data on any of the provisionally listed color additives supported "permanent" listing, termination of the provisional listing, or requirements to submit additional data. This review led to the termination of the provisional listing for FD&C Red No. 4 and carbon black, by notices published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41852, 41857), and the "permanent" listing of 20 color additives by notices published in the FEDERAL REGISTER between September 23 and November 30, 1976.

The review also led to the conclusion that, while the data did not appear to establish a basis for concern about the safety of the remaining 52 provisionally listed color additives, the available data, evaluated by contemporary standards, do not support "permanent" listing at this time. The regulation prescribes the requirements for testing and a schedule for submission of the results of that testing to FDA and will enable FDA to resolve the status of the remaining provisionally listed color additives. As stated above, three factors largely account for the continuation of the provisional list today. The Commissioner believes that it is important for the public to understand the historical reasons for the continuation of the provisional list.

Congress initially established a closing date for the provisionally listed color additives 2½ years after the effective date of the Color Additive Amendments of 1960 (July 12, 1960). The 2½-year period was chosen based on the expectation that that period would be adequate to conduct the necessary testing on all color additives then in commercial use and, under the terms of the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 706 note)), entitled to be provisionally listed. In fact, however, the 2½-year period established by Congress was too brief to permit the completion of necessary scientific investigations, including some chronic animal-feeding studies which run 2 to 3 years, and evaluation of those studies by FDA. Thus, it was almost inevitable that extensions of the closing date for certain of the provisionally listed colors would become necessary even if there had been no change in scientific requirements based upon improvement in scientific testing and evaluation techniques.

When the initial closing dates for the provisionally listed color additives occurred in January 1963, it was necessary to postpone the closing dates. This was because some chronic feeding studies were incomplete and additional chemistry data were required to establish specifications for the provisionally listed color additives. In several instances, postponements were necessary because precise assay methods had not yet been validated. In short, the gaps in the data on these color additives generally did not go to the central question of their safety for human consumption. Although the missing data obviously were needed before final determinations about "permanent listing" could be made by FDA, continued provisional listing for these color additives was consistent with the intent of Congress in providing for the provisional list. Extensions of the provisional list were also granted in a few instances because equivocal results were obtained from chronic feeding studies that required additional long-term study to resolve. This was the case, for example, with FD&C Red No. 4.

A second factor contributing to the several postponements of the closing dates for certain provisionally listed color additives was the unsuccessful efforts of FDA to obtain information about the formulation of all cosmetic products in which color additives were used. These efforts began formally in March of 1966 when former FDA Commissioner James Goddard, M.D., advised the Toilet Goods Association (the predecessor to the Cosmetic, Toiletry, and Fragrance Association) that the so-called "Harvey list" color additives, 21 in number, could not be listed "permanently" without information on the formulations in which the color additives were used. Further consideration of "permanent" listing for the provisionally listed color additives was held in abeyance pending litigation on the issue whether FDA had legal authority to require premarketing clearance of finished cosmetic products. In 1969, the United States Court of Appeals for the Second Circuit held that the provision of the color additive regulations requiring premarketing clearance of finished cosmetic products was not authorized by section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376) (*Toilet Goods Association* v. *Finch*, 419 F.2d 21 (2d Cir. 1969)). The Food and Drug Administration did not appeal this decision. Subsequent consideration of the 21 "Harvey list" color additives in light of changed scientific standards for the evaluation of food and color additives resulted in demands for additional data on these and the other provisionally listed colors, and in further postponements of the closing dates for them.

The most important reason for the several postponements of the closing dates for the provisionally listed colors is the dynamics of scientific criteria for the toxicological evaluation of chemical substances. The tools for the safety evaluation of products have greatly improved since 1960. Thus, a color additive first proposed for use today would be studied to determine the potential of the color to induce cancer, effects on reproduction or the fetus, and other types of toxic effects. The scientific techniques for assessing and evaluating these effects are far more sophisticated than those commonly employed in the 1960's. To assure that the

safety of the provisionally listed colors had been evaluated in accordance with contemporary scientific standards before they were listed "permanently," FDA has imposed additional requirements on the sponsors of the additives as significant scientific improvements have occurred. These requirements were imposed as a condition of continued provisional listing. As a result, FDA knows substantially more about the toxicity of most provisionally listed color additives than would be the case had decisions about "permanent" listing been made in the early 1960's.

The scientific investigations and tests prescribed in this regulation conclude a process that has been underway for some time, albeit concededly in a less systematic and vigorous fashion. This process of updating the data on the safety of food ingredients—food additives, substances generally recognized as safe (GRAS), and color additives—as scientific standards for evaluating the safety of such products improves, will continue as long as science remains dynamic.

2. Two comments, one from a consumer and one from a consumer group, asserted that the proposed extension of the provisional list is not authorized by the Federal Food, Drug, and Cosmetic Act and is contrary to the intent of Congress in enacting the Color Additive Amendments of 1960. The comments further implied that the 52 provisionally listed color additives are unsafe.

In paragraph 1 of this preamble, the Commissioner discusses the primary reasons why the provisional list has been extended since 1960. The Commissioner believes that previous extensions were granted for valid reasons and, though Congress probably did not anticipate in 1960 that color additives would be provisionally listed in 1976, further extension of the list is nonetheless consistent with the overriding objective of Congress in enacting the amendments—to have the safety determinations on color additives made on the basis of the best available data.

The implication in the comments that the 52 colors subject to this regulation have not been tested is erroneous. Delays both by sponsors in submitting necessary data to FDA and by FDA in evaluating those data and advising the sponsors of those evaluations have concededly contributed to the necessity for extensions of the provisional list. As indicated in paragraph 1 of this preamble, however, the scientific investigations previously required or required by this regulation as a conditon for continued provisional listing are necessary primarily because of improving scientific standards for evaluating the safety of substances added to food, drugs, and cosmetics. The Commissioner concludes that continued provisional listing for the 52 color additives is consistent with the objectives of Congress in enacting the amendments in 1960 and the agency's responsibilities to protect the public health.

3. One comment contended that the proposal was inadequate because it failed to disclose the empirical data and underlying considerations for the proposed actions, as required by the Administrative Procedure Act, (APA) (5 U.S.C. 553) and the case of "National Welfare Rights Organization v. Mathews," 553 F. 2d 637 (D.C. Cir. 1976). The comment cited as particularly deficient the Commissioner's conclusion that continued use of the 52 provisionally listed colors under the intended conditions of use would not present a hazard to the public health, and the comment asserted that the Commissioner's conclusion, without citing the empirical data and underlying considerations on which it is based, will deprive a court of an adequate administrative record to review the final regulation. Finally, the comment contended that FDA should issue a "more informative" proposal to comply with the requirements of the APA.

The Commissioner has carefully considered the "National Welfare Rights" case cited by the comment, as well as other pertinent legal authority, and concludes that the proposal complies with the requirements of the APA. The preamble to the proposal, the substantial background material, including toxicological reviews of many of the 52 color additives, which were placed on file with the Hearing Clerk, and publication of the proposal in the FEDERAL REGISTER adequately apprised the public of the basis for the proposed action and the underlying facts and considerations that support it. Furthermore, all the safety and functionally data on the 52 color additives have been available to the public under § 8.9(a)(1) (21 CFR 8.9(a)(1)).

The comment contended that the Commissioner's conclusion lacks empirical support and that this prevents intelligent comment or judicial review. The Commissioner's conclusions are based on review of the available data on each of the color additives and the application of standard scientific and toxicological criteria. It obviously is not practicable to reproduce the voluminous safety data on each color additive in the FEDERAL REGISTER, nor would a mere summary of those data enable interested persons to assess the validity of the Commissioner's conclusions. The Commissioner encourages persons who believe that any of the 52 provisionally listed color additives should not be so listed to review the safety data on any such additive and to petition FDA to terminate the provisional listing. Any such petition will receive careful and prompt review.

4. Several comments contended that color additives provide no "benefit" to the public and that their use is purely cosmetic and concluded, therefore, that their use should not be sanctioned by FDA. Other comments opposed the use of any artificial color additives and stated their preference for "natural" foods and food ingredients. One comment cited a recent Gallup poll in which the majority of the persons surveyed favored banning food (and presumably color) additives used only to improve the appearance of food.

A number of comments, on the other hand, supported the use of color additives in food. One comment stated that "We need some color in life. So what if it may be a bit risky. Humanity has lived with these things until this the 20th century." Other comments pointed out that their relatives have eaten colored food for years without suffering adverse effects and suggested letting the consuming public decide if it wants to eat colored foods.

The Commissioner advises that it is Congress that has made the judgment that color additives that have been proved safe should be permitted in food. The role of FDA under the Federal Food, Drug, and Cosmetic Act is not to make the value judgment about whether color additives are "beneficial," but rather to evaluate the data submitted in support of color additive petitions and to approve for use in food, drugs, cosmetics, and devices only those colors that it is reasonably certain are safe. In short, Congress has made the collective judgment that color additives are "beneficial" and should be permitted to be used if proved safe.

The Commissioner recognizes that consumers are not always in a position to decide for themselves if they wish to ingest foods that contain color additives or to distinguish among foods on the basis of the color additives that they contain. Congress, in the Federal Food, Drug, and Cosmetic Act, has permitted most foods to avoid specific labeling of the color additive used. The phrase "artificial color" in the ingredient statement on a food label complies with section 403(k) of the act (21 U.S.C. 343(k)). Thus, a consumer cannot ordinarily determine from a food's labeling which color additives it contains. Additionally, consumers are ordinarily not in a position to determine whether food served in restaurants, institutions, or in someone else's home contains color additives. Thus, it is essential for the protection of consumers that only those colors whose safety is established be permitted in food.

The Commissioner also advises that the absence of observed adverse effects in persons who have consumed food with added color for years cannot be taken as proof of the safety of those colors. Some adverse effects that occur from the ingestion of unsafe chemical substances appear only after many years of exposure. Observable adverse effects occurring immediately after ingestion are unusual. Furthermore, the casual observation of a small group of persons who appear to have suffered no ill effects from consumption of food with added color is not a proper scientific basis for extrapolation to the general population.

Finally, the Commissioner advises that "natural" foods and food ingredients are not necessarily safer than artificial ones. Many natural foods are harmful if ingested in sufficiently large quantities. Additionally, many synthesized ingredients are chemically identical to substances that occur naturally. In short, the notion that all natural foods are safer than all artificial foods is not supported by available scientific data.

5. One comment stated that FD&C Blue No. 1 and FD&C Green No. 3 are carcinogenic and objected to continued provisional listing for these color addi-

tives. In support of this position, the comment referred to pages 106–107 of "Environmental Cancers of the Urinary System" by Dr. Wilhelm C. Heuper. In that book, Dr. Heuper states:

> In view of the occurrence of bladder cancers in producers of widely used paper and food colors (the diphenylmethane dye auramine, and the triphenylmethane dye fuchsin), and of sarcomas of the subcutaneous tissue in rats after their subcutaneous injection (Case et al., 1954; M. H. C. Williams, 1958, 1962; Williams and Bonser, 1962; Walpole, 1963) and the reported occurrence of a bladder cancer in a German producer of Brilliant Blue, another triphenylmethane dye (Bundesministerium für Arbeit, 1957), adequate human and experimental evidence seems to be on hand for reassessing the significance of sarcomas of the subcutaneous tissue induced in rats by several triphenylmethane dyes.

Studies in which a substance is injected subcutaneously into test animals are not ordinarily considered appropriate tests to evaluate the safety of color and food additives. This view has been recognized by the World Health Organization and FDA's Advisory Committee on Protocols for Safety Evaluation (World Health Organization Technical Report Series (Geneva), No. 348, 1967; Toxicology and Applied Pharmacology 20:419, 1971).

Dr. Heuper also refers to a single reported incident of bladder cancer in a worker employed in a facility manufacturing "Brilliant Blue" in Germany. The sole authority for this reference is a 1957 German publication, which was not included with the comment and which is not readily available to FDA. In any event, the isolated report of cancer in an industrial worker dating back to 1957 is not suggestive of a potential for FD&C Blue No. 1 to induce cancer in man when ingested under ordinary conditions of use. The rate and conditions of exposure are different and, as noted, the incident was apparently isolated.

Finally, the chronic feeding studies on FD&C Blue No. 1 and FD&C Green No. 3, although inadequate by contemporary standards, do not suggest that either color may be a carcinogen. Without more substantial data to establish that either color is likely to be carcinogenic, the Commissioner concludes that continued provisional listing for FD&C Blue No. 1 and FD&C Green No. 3 does not present a hazard to the public health. New chronic feeding studies will be conducted on these two color additives under this final regulation as a condition of continued provisional listing. The results of those studies will permit the comment's hypothesis to be tested.

6. One comment objected to the proposed extension of provisional listing for various azo dyes and specifically named FD&C Yellow No. 5 and FD&C Yellow No. 6. Citing a reference from "Occupational and Environmental Cancers of the Urinary System," the comment stated that, according to Dr. Heuper, there is reason to believe that azo dyes contain various carcinogenic amines, including β-naphthylamine.

The Commissioner concurs with the comment's statement that β-naphthylamine is considered to be a carcinogen. Two colors, Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10, which were synthesized from β-naphthylamine, were prohibited by FDA from use in drugs and cosmetics because of a finding that they might contain β-naphthylamine. Accordingly, the Commissioner views with concern the possibility that any color additive for food, drug, or cosmetic use might contain the impurity.

β-Naphthylamine is an intermediate that is used in the production of diazotized compounds for industrial use. These compounds are not, however, used in the production of colors intended for use in food, drugs, or cosmetics. β-Naphthylamine is not expected to be present in color additives, therefore, except as a contaminant. The Commissioner is unaware of any data that would indicate that FD&C Yellow No. 5 or FD&C Yellow No. 6 might contain any β-naphthylamine as a contaminant of the finished color or any of the raw materials or as a result of intermediate steps in their production.

However, upon further review of the data on each of the azo dyes, the Commissioner concludes that there are five colors that could possibly contain low levels of β-naphthylamine as impurities—D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, D&C Red No. 13, and D&C Red No. 34. These colors are synthesized from 2-amino-1-naphthalenesulfonic acid which may contain β-naphthylamine.

To resolve the questions raised by this comment, the Commissioner has requested that the petitioners promptly provide to FDA data about the possible contamination of 2-amino-1-naphthalenesulfonic acid and each of the five colors with β-naphthylamine.

Furthermore, in view of the concern that β-naphthylamine may be present in the color additives, FDA has initiated immediate action to investigate the possibility. It will promptly conduct analyses of samples of each of the five colors and 2-amino-1-naphthalenesulfonic acid using very sensitive methods. The Commissioner is continuing the provisional listing for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 because the short period of time required to resolve this question will not present a hazard to the public health. If data become available, either from investigation by FDA or from the petitioners, that indicate that β-naphthylamine may be present in any of the color additives, the Commissioner will take immediate action to protect the public health. The Commissioner advises that FDA is also examining the data on D&C Red No. 34, which was the subject of an order, published in the FEDERAL REGISTER of November 23, 1976 (41 FR 51592), "permanently" listing the color to determine if it might contain β-naphthylamine. The Commissioner will take immediate action to protect the public health if the data indicate that D&C Red No. 34 might contain β-naphthylamine. In the meantime, the Commissioner is staying the order "permanently" listing D&C Red No. 34.

7. Several comments objected to the use in food of any color additive that has not been proved "completely" or "absolutely" safe.

The Commissioner advises that while the objective of "completely" or "absolutely" safe color additives is a worthy one, it is beyond the capability of science to assure complete safety. There is always some risk, however slight, in using in food any substance—natural or artificial, color or other additive. In recognizing this, Congress has provided that FDA must be "reasonably certain" that a food or color additive will be safe when used as intended. Although FDA applies demanding scientific criteria to determine whether color additives are safe, it is not possible to be absolutely certain that consumption of any color additive or other ingredient poses no risk whatever to health.

8. Several comments questioned the basis on which FDA makes judgments about the safety of color additives. A metallurgist conducting research to define the carcinogenic constituents of industrial atmospheres suggested that unneeded alarm is caused by regulatory action taken without substantial experimental evidence. This comment also expressed skepticism about extrapolations made from data derived from tests in animals and applied to man. Another comment suggested that FDA bans substances used in food without justifiable cause and does so merely out of fear that they are carcinogens. The comment noted that test animals are customarily fed very high amounts of the substance being tested.

The Commissioner points out that the testing of substances such as color additives in animals to determine the probable effects of the substance in humans is a longstanding and generally accepted practice, especially for substances such as food and color additives that would ordinarily not be tested in humans. Although extrapolating from animal experience to human risk is an uncertain process, FDA must rely on animal tests as a predictor of the safety of new food ingredients in humans. The Commissioner advises that the test animals are fed seemingly high doses of the test substance to compensate for the lack of sensitivity of tests in relatively small numbers of animals to detect hazards among the much larger human population. Although this technique is not without its difficulties, it is widely employed by the scientific community and is generally accepted as appropriate.

9. A few comments contended that FDA should ban any substance suspected of causing harm.

The Commissioner disagrees. When a safety issue is raised about a compound that FDA previously has approved, the agency must review the question in a reasoned and scientific manner. This approach is rooted in common sense, because it is not difficult to raise questions about the safety of a food substance. If unevaluated questions produced an immediate and uncritical response, the nation's food supply would be in constant chaos, with products

continually being banned and, possibly upon reevaluation, later returned to the grocers' shelves.

10. A few comments suggested that FDA or outside laboratories, rather than the sponsors of color additives, should conduct tests on the provisionally listed color additives. In addition, FDA has received a request from the Cosmetic, Toiletry, and Fragrance Association (CTFA) and the Pharmaceutical Manufacturers Association (PMA) that FDA undertake the testing of 25 provisionally listed drug and cosmetic colors required by the regulation.

The Commissioner concludes that under the Federal Food, Drug, and Cosmetic Act, the primary responsibility for conducting (as distinct from final evaluation) studies to support product applications filed with FDA lies with the sponsors of those applications. Although FDA has, in the past, conducted some studies on color additives, it has not, since passage of the Color Additive Amendments of 1960, assumed the massive responsibility to conduct all such studies. The Commissioner believes that such an undertaking would be an inefficient use of the limited resources of FDA and that other, less costly ways of ensuring the reliability, accuracy, and completeness of submitted data are preferable.

For example, FDA is currently implementing a bioresearch monitoring program designed to audit and upgrade the quality of the studies conducted by testing laboratories and to ensure the basic integrity and reliability of the data submitted to FDA as a result of studies performed in these laboratories. The Commissioner is confident that this far-reaching program will improve the performance of nonclinical laboratories and assure a high level of compliance with the applicable legal and scientific standards. The request of CTFA and PMA and the Commissioner's response thereto are discussed in greater detail elsewhere in this preamble.

11. One comment opposed the use of all colors in foods because of the alleged relationship between ingestion of food and color additives and hyperkinesis in children. The comment called for the labeling of all ingredients used in food.

Behavioral disorders related to the hyperkinetic syndrome are found in children of all socioeconomic groups and in most countries throughout the world. A conservative estimate would be that moderate and severe disorders are found in as many as 3 out of every 100 elementary school children. More males than females appear to be affected. The major symptoms of the disorder are an increase of purposeless physical activity and a significantly impaired span of focused attention. The inability to control physical motion may generate other behavioral consequences. It has been suggested that there are several etiological subgroups within the syndrome.

In 1975, Dr. Ben F. Feingold stated in "Why Your Child is Hyperactive" that artificial colors and flavoring agents produce hyperactive behavioral symptoms in genetically predisposed children. In addition, Dr. Feingold concluded that total withdrawal of the artificial substances through the Feingold Kaiser-Permenente (K-P) diet can be of therapeutic value in the treatment of between 25 and 50 percent of the children with hyperkinesis.

While these reports are anecdotal, the possible relationship between food additives and the hyperkinetic syndrome in children is an important health issue that is currently being studied by various agencies within the Department of Health, Education, and Welfare and by outside groups. One recent study of the Feingold hypothesis was conducted by the Food Research Institute of the University of Wisconsin. The observations and data from this study are currently being collated and evaluated.

The Interagency Collaborative Group on Hyperkinesis (ICGH), composed of scientists from FDA, the National Institutes of Health, the National Institute of Mental Health, and the National Institute of Education, was established in the summer of 1975 to assess all the available data on the possible association between hyperkinesis and diet and to make recommendations for any additional research indicated. Scientists from FDA provided the leadership in organizing the ICGH and in the preparation of the First Report of the Preliminary Findings and Recommendation.

On February 23, 1976, the members of the ICGH prepared and approved three specific research proposals to carry out the recommendation of the report. The studies proposed were as follows:

(1) A Dietary Challenge Study of Artificial Food Colors and Flavors in Children (1 to 5 years old) with Behavioral Disturbances.

(2) A Dietary Challenge Study of Artificial Food Colors and Flavors in School-Age Hyperkinetic Children.

(3) Support to Obtain Data, Results and Interpretation of a Study of Food Additives and Hyperactivity in Children.

The Bureau of Foods, FDA, has provided $37,506 for the funding of study 3, and the National Institutes of Health has provided $106,800 for the funding of a challenge study in children ages 1 to 5 years.

The Commissioner notes further that FDA has consistently supported complete and more informative ingredient labeling of foods. For example, since 1941 FDA has required special dietary foods for infants to include the name of each ingredient, including colors, on the label; and FDA is exploring other ways to achieve complete ingredient labeling. The agency has also supported legislation that would require specific label designation of all colors in food. The Commissioner therefore concurs with the comment on this point and advises that FDA will continue to seek ways to provide more informative food labeling to consumers.

12. The majority of comments were on the action taken by FDA to terminate the provisional listing for FD&C Red No. 4, previously used to color maraschino cherries and short-term ingested drugs. These comments, mainly from cherry growers and industrial users of maraschino cherries, e.g., fruit-cake manufacturers, noted the adverse economic consequences that they assert will result.

The Commissioner advises that the potential adverse economic impact of the decision to terminate the provisional listing of FD&C Red No. 4 was fully considered before FDA acted. Representatives from the National Cherry Growers Association and the Maraschino Cherry and Glace Fruit Association met with FDA officials on several occasions before the action was taken. The Commissioner weighed the possible economic impact of the action but concluded that the Federal Food, Drug, and Cosmetic Act required that priority be given to considerations of public health. The basis for the agency action in terminating the provisional listing is explained fully in the FEDERAL REGISTER of September 23, 1976 (41 FR 41852).

13. One comment from a trade association contended that the available data on the 52 provisionally listed color additives are adequate to support "permanent" listing.

The Commissioner disagrees. These data were recently reviewed in light of contemporary standards by FDA scientists, who concluded that "permanent" listing for the 52 color additives would not be appropriate at this time. The comment offered no data in support of its argument, and it is therefore rejected.

14. The Certified Color Manufacturers Association (CCMA) has advised FDA that it will undertake the chronic feeding studies required under § 8.505(d) of this final regulation on FD&C Blue No. 2, FD&C Green No. 3, and FD&C Yellow No. 6. It has submitted a proposed protocol for these studies, which FDA has reviewed. Subject to a few minor changes, the proposed protocol is satisfactory to FDA.

15. In its comment, CTFA stated that it was reviewing the studies conducted on the D&C color additives and that it would advise FDA shortly of the results of the review. It stated that it would also suggest to FDA "how the body of information on the colors can be supplemented to permit a sound evaluation of their safety."

The Commissioner advises that, in his view, additional studies are required on the D&C colors to assure that they are safe on the basis of current scientific criteria. This does not mean, however, that the provision of additional data from studies already completed might not provide assurance of the safety of the color additives, assuming of course, that the data are derived from studies conducted in accordance with contemporary standards for the evaluation of food and color additives. If adequate additional data are provided on a particular additive, the Commissioner would delete the requirement for studies from the final regulation. The Commissioner emphasizes, however, that the time requirements in § 8.505 will not be altered, unless "extraordinary circumstances" are shown, either to permit submission of data or to allow for evaluation of those

data. The data must, therefore, be submitted to FDA as soon as possible and the requirements of § 8.505 complied with; failure to comply with § 8.505 will result in termination of the provisional listing of the affected color additive.

16. Several comments commended FDA for providing the public the opportunity to comment on the provisionally listed color additives and they generally supported the provisions of the proposal. Other comments supported further testing of food and color additives and the efforts of FDA to require such testing.

17. A number of comments were received from the petitioners for the 52 provisionally listed color additives. Some of the specific comments objected to certain proposed requirements, including the stringent time limitations for completion of studies; others stated that the requirements could be met by the petitioners. A few comments were accompanied by scientific data and literature submitted in support of the comments' assertion that the data on particular color additives were adequate to establish their safety and justify "permanent" listing.

The Cosmetic, Toiletry, and Fragrance Association, one of the petitioners for many of the 52 provisionally listed color additives, advised that the proposed requirements in § 8.505(a) pertaining to eye-area studies were reasonable. It stated that the results of those studies would be submitted to FDA within 45 days of the effective date of this final regulation and that the July 1, 1977 closing date for those color additives was appropriate as long as FDA promptly reviewed the final reports from the eye-area studies.

The Commissioner advises that high priority will be given to the review of the reports of data concerning the provisionally listed color additives. If those reports are received by the dates established in § 8.505 for their submission, FDA will make final determinations about "permanent" listing and issue notices implementing those decisions by the closing dates established in § 8.505. If the reports are not received in timely fashion, the use of the color additive will be terminated immediately.

18. The Certified Color Manufacturers Association commented that proposed § 8.505 appeared "to be written in such a fashion as to require that all co-petitioners agree to perform the steps requisite to satisfying the conditions and that all co-petitioners actually perform the studies." Because all co-petitioners may not share the same interests, the CCMA suggested that § 8.505 be revised to require that at least one petitioner for each color agree to perform, and actually undertake and complete the required studies.

The Commissioner concurs with this suggestion and § 8.505 is revised accordingly.

19. A comment from a trade association stated that adequate specifications for the color additives must be established before beginning any chronic feeding studies. It suggested that the closing dates for any colors that require resolution of chemistry deficiences, in addition to toxicological tests, should be calculated from the date of FDA approval of the chemical and analytical data. A comment from a consumer group contained a parenthetical statement that "it is appalling that for 17 years FDA has explicitly sanctioned the continued use of dyes without even knowing their chemical identity."

The Commissioner advises that, in general, FDA already has adequate knowledge of the identity of each of these colors and has established appropriate specifications. There remain, however, a few issues of identity of minor constituents of some colors that require resolution before the color additives can be listed "permanently."

In the case of graphite, for example, FDA is aware of literature references that indicate that certain types of graphite may contain polynuclear aromatics (PNA's). Because some PNA's are carcinogenic, the petitioner has been requested to supply data capable of demonstrating whether graphite contains PNA's. The Cosmetic, Toiletry, and Fragrance Association has submitted data from the analysis of one batch of graphite that indicated that no PNA's were found using an analytical method with a reported sensitivity of two parts per billion (ppb). The results of this analysis of one batch of graphite from one supplier are however, not adequate to establish the absence of PNA's. Additionally, other unresolved questions related to the analytical method remain. Because, however, there are no definite data that would indicate graphite is likely to contain some amount of PNA's, the Commissioner concludes that its provisional listing may safely continue for the short time necessary to develop and submit the necessary data for graphite.

The remaining eight color additives that require additional chemistry data are subject to certification. These colors are complex chemicals synthesized from various petrochemicals. The purity of the color additives ranges from 85 to 95 percent for the pure color. The remaining 10 to 15 percent is composed almost entirely of water and salts of chlorides and sulfates. In most cases the remaining small fraction of the color not accounted for by one of these substances has also been identified. Because of the complexity of the starting materials and their reactions, however, small amounts of reaction compounds that are not readily identifiable may be formed during synthesis of the color additive. The analytical data are necessary to permit identification of these compounds in color additives and to determine whether they were in the samples of the lots used for toxicological testing.

Pending resolution of these questions, the samples of each of the color additives used in the toxicological tests will be used as templates against which to judge the safety of these minor components. Occasionally, during the certification of a batch of a color, minor amounts of unknown substances are detected. The sample of the color used in the toxicological tests is then analyzed in the same manner to determine whether the unknown is also present. Thus, the toxicological sample serves as a "specification", i.e., a reference standard for judging batches being certified. During the brief period necessary to resolve the chemistry questions for the eight certified colors, the Commissioner concludes that continuation of provisional listing will not present a hazard to the public health.

The Commissioner rejects the suggestion that the closing date for those colors requiring both chemistry data and chronic toxicity data be determined from the submission of the former. Although the Commissioner would agree that the development of specifications of the test material before testing is ordinarily preferable, he does not agree that such an approach is appropriate in this case. The manufacturers of these colors are knowledgeable about their production and purification and will be able to reproduce colors that will comply with specifications developed from the toxicological samples, whether they be from the earlier studies or the new studies that are being required. The manufacturers are in the position to establish the purity of the color used for testing and, thus, its specifications.

20. The Cosmetic, Toiletry, and Fragrance Association questioned the need for a 90-day rabbit dermal study on bismuth oxychloride and submitted additional data to FDA in support of its position. It noted that the material on file with the FDA Hearing Clerk did not include a memorandum discussing the basis for the proposed requirement for the 90-day rabbit dermal study.

The additional data submitted by CTFA have been evaluated and are not adequate to resolve the questions about bismuth oxychloride which generated the proposed requirement. Accordingly, the requirement for a 90-day rabbit dermal study on bismuth oxychloride is retained in the final regulation. Bismuth oxychloride will continue to be provisionally listed pending receipt and evaluation of the studies required under § 8.505.

21. In its comment, Combe, Inc., the petitioner for bismuth citrate, stated that it was prepared to submit a protocol and conduct the short-term (90-day) absorption study in humans, in accordance with proposed § 8.505(b). Combe questioned, however, whether the proposed requirement for a 90-day rabbit dermal study would provide useful data on the safety of bismuth citrate and suggested deletion of the requirement. In support of its request, Combe submitted several articles from scientific journals discussing various aspects of the safety of bismuth citrate.

The Commissioner advises that the petitioner misconceived the purpose of the dermal study. The primary purpose of the study is to determine whether bismuth citrate is toxic when repeatedly applied topically. This study is particularly pertinent in the case of a color additive such as bismuth citrate which is

used in products intended for repeated topical use (hair dyes). The chemistry and analytical data submitted by the petitioner are useful but do not remove the need for the dermal study. The requirements contained in proposed § 8.505 pertaining to bismuth citrate are, therefore, retained in this regulation.

22. The petitioner for caramel questioned the need for subchronic and chronic dermal studies on the color additive. In support of this position, the petitioner referred to a letter received on April 12, 1976, from FDA advising that data for eye-area studies were necessary to permit a final determination to be made. The petitioner stated that the eye-area studies are currently being conducted. The need for dermal studies was questioned because of the absence of a statement to that effect in the letter received on April 12, 1976. The petitioner asked for a reexamination of this requirement.

The available data for caramel have been reexamined, and the Commissioner advises that those data are not adequate to support "permanent" listing of caramel for use in externally applied cosmetics. A 90-day rabbit dermal study and a lifetime mouse skin painting study are therefore necessary for caramel. The Commissioner concludes that the requirements for this color, set forth in § 8.505 (b) and (d) below are appropriate, and continued provisional listing of this color will be based on compliance with the requirements.

23. Three commentors, CTFA, CCMA, and Hilton Davis Chemical Co. asserted that they are not aware of the deficiencies in the chemistry data on the 15 color additives listed in proposed § 8.505(c) and that, without a comprehensive list of those deficiencies, they are unable to comment on this aspect of the proposal.

The petitioners for the 15 colors that require additional chemistry data have been advised repeatedly over the years of the specific deficiencies. The deficiencies were discussed at length in a meeting on January 29, 1976, with representatives of CTFA and Hilton Davis Chemical Co. Letters were sent to each of the petitioners on January 29, 1976, and February 5, 1976, outlining the various deficiencies. Subsequently, the petitioners and their designees submitted data to the Division of Food and Color Additives, Bureau of Foods, indicating that work had been initiated to resolve the various chemistry deficiencies. Meetings were held on March 18, 1976, and May 4, 1976, and at other times, to discuss the progress of this work. A letter was sent to the petitioners, dated May 14, 1976, updating the status of the chemistry data requirements for these 15 color additives. Subsequently, data were submitted for some of the colors. These data were, however, generally received too late for consideration in the drafting of the proposal. The correspondence with the petitioners detailing the chemistry deficiencies and memoranda of the meetings with the petitioners were placed on file with the Hearing Clerk, Food and Drug Administration, when the proposal was published.

The Commissioner concludes that the above-noted actions have provided sufficient notice to the commentors concerning the chemistry deficiencies for the 15 colors. Additionally, a letter has recently been sent to each of the involved petitioners commenting on the data they recently submitted and advising them of any additional data necessary to resolve chemistry deficiencies. Copies of these letters have been placed on file with the Hearing Clerk.

A review of the submitted data by FDA indicates that the data resolve the chemistry deficiencies for a number of colors, specifically: FD&C Yellow No. 6, D&C Red No. 27, D&C Red No. 28, D&C Orange No. 5, and logwood. The requirement for the submission of chemistry data for these five colors and for D&C Orange No. 11, which was inadvertently included in the proposal, is deleted from § 8.505(c) of the final regulation. The remaining 9 color additives—D&C Yellow No. 10, D&C Red No. 6, D&C Red No. 7, D&C Red No. 30, D&C Orange No. 4, D&C Blue No. 6, Ext. D&C Yellow No. 1, Ext. D&C Green No. 1, and graphite—continue to have deficiencies in the chemistry data that require submission of additional data to support their "permanent" listing. The Commissioner concludes that the time requirements in § 8.505 for the submission of these data, as originally proposed, are reasonable and they are retained in the final regulation. Under the regulation, one of the petitioners, or some other interested person through the petitioners, must agree by March 7, 1977, to conduct the necessary studies and must submit the required chemistry data and analytical methods to FDA by August 3, 1977. Continued provisional listing is conditioned upon satisfactory completion of these two requirements.

The closing dates for logwood and graphite have been extended to October 31, 1977, because of the time required to issue final regulations.

The closing dates for the color additives that require chemistry data and new chronic feeding studies have been extended to January 31, 1981.

24. On December 30, 1976, CTFA and PMA filed a request, denominated as a "citizen petition," with FDA under section 706 of the act (21 U.S.C. 376) and § 8.37 (21 CFR 8.37). They requested that FDA conduct the required scientific studies for 25 provisionally listed drug and cosmetic (D&C) color additives. On January 26, 1977, representatives of the associations met with FDA officials to discuss further their request.

The associations contend that FDA can best assure that the testing required by the regulation is done expeditiously and properly if it conducts the studies itself. The request notes that FDA would not be required to conduct all the studies in its own facilities, but could give contracts to independent laboratories to conduct certain studies.

A second aspect of the CTFA–PMA requests relates to the method of financing the required tests. The Commissioner's response to that aspect of the request is discussed later in this paragraph.

The Commissioner rejects the request insofar as it pertains to FDA's undertaking to conduct or arrange for the studies and advises that interested persons, not FDA, must be responsible for conducting the tests required by the regulation. The Commissioner acknowledges that in certain circumstances, which he is not persuaded exist here, it may be appropriate for FDA itself to sponsor toxicological testing on products it regulates. In fact, FDA has, in the past, conducted such studies on certain color additives. In recent years, however, FDA has not simultaneously conducted large numbers of toxicological studies on any compounds. Instead, that responsibility has been left to the proponents of the use of regulated products—in this case the petitioners for the 52 provisionally listed color additives.

The Commissioner believes that in this case the agency's limited resources can best be employed in monitoring the studies and in evaluating the results of those studies. A significantly greater expenditure of agency manpower, not compensable by increasing the certification fee, would be required if FDA were to undertake the responsibility for conducting the studies. Obviously, FDA facilities would be inadequate and arrangements would have to be made with independent laboratories to conduct some, if not all, of the studies. This in itself would require a substantial expenditure of agency resources.

The Commissioner recognizes that CTFA and PMA have offered to cooperate with FDA in ensuring prompt commencement of the studies, including the submission of test protocols, specifications, information, recommendations on independent laboratories, and assistance in monitoring the studies. Nonetheless, the Commissioner concludes that even with such assistance, the resources of FDA that would be required exceed those currently at the Commissioner's disposal.

The Commissioner notes also that there is no legal obligation imposed on FDA to undertake the studies. Although FDA has conducted such studies on occasion and may do so in the future, the Federal Food, Drug, and Cosmetic Act imposes the responsibility for testing on the sponsors of regulated products, not on FDA.

The Commissioner is aware that in recent years, numerous persons have argued that the overall quality, reliability, and integrity of studies conducted to support product applications filed with FDA would improve if FDA or some "disinterested" third party conducted the testing. The agency has expressed skepticism about this suggestion, believing instead that its role should be limited to establishing standards for the conduct of such studies, e.g., good laboratory practice regulations, monitoring the studies while they are in progress (through laboratory inspections), and evaluating the results of those studies. The Commissioner continues to maintain that the advantages of such a program would not justify the burdens on FDA

that would result from a "third party testing" approach.

Finally, the Commissioner notes that at the meeting on January 26, 1977 referred to above, both CTFA and PMA expressed a willingness to undertake the required studies if FDA concluded that it could not or should not assume that responsibility. However, CTFA and PMA also stated that the aspect of their request that relates to the financing of the studies can be considered separately and, in their view, is meritorious.

The two associations note that imposition of a research charge on the certification fee for the 25 provisionally listed color additives covered by their request would fairly distribute the cost of the testing. They point out that the higher certification fee charged to color manufacturers would be passed on directly to the users of color additives in the form of a higher price per pound. The associations also point out that a similar mechanism was used by FDA to finance the studies it conducted on color additives in the 1950's.

The Commissioner agrees that distributing the cost of required testing on regulated products among all who benefit from the products' availability (i.e., all manufacturers and users) is a desirable objective. However, the Commissioner has not fully evaluated the CTFA–PMA request nor have interested persons been afforded the opportunity to comment on the request. Accordingly, the Commissioner concludes that it would be inappropriate to act on the request at this time.

Because, however, the request does appear to have at least theoretical merit, the Commissioner believes that it would be advantageous to obtain the views of interested persons on the financing aspects of the CTFA–PMA request. In particular, the Commissioner solicits comment on the following questions related to the request:

a. Should the request be granted by FDA?

b. If so, how should the cost of conducting the studies be distributed? Specifically, should the same research charge be added to the certification fee for each color or should each color additives being tested "pay its own way"?

The views of interested persons on these questions and all other aspects of the request are solicited. To permit a prompt resolution of this matter, those views should be submitted to the Hearing Clerk, FDA, by March 7, 1977.

25. Three comments, all from trade associations, contended that the proposed closing date of December 31, 1980, for those provisionally listed color additives that require new chronic feeding studies was unrealistic. The comments questioned whether the petitioners or FDA could meet that deadline. The comments noted the possibility of unavoidable delays and difficulty in locating testing facilities and qualified personnel to conduct the studies. One comment stated that 42 months was not sufficient to conduct and evaluate the results of the studies and noted that "the FDA's proposed deadlines could be met only if all the necessary steps were accomplished without any unforeseen problems arising and with the imposition of an undue amount of pressure on the responsible parties." A closing date of June 30, 1981, was suggested by one of the comments.

The Commissioner concludes that the comments have not established that the December 31, 1980 closing date is unreasonable or unrealistic. The Commissioner agrees with the comments insofar as they recognize that conscientious, concerted, and forceful action will be necessary to meet the deadlines imposed by the final regulation. This was the Commissioner's intent in proposing the strict schedule in § 8.505. The Commissioner notes also that the strict schedule is applicable to both the petitioners and FDA. The period allotted for FDA to review the data and to make final determinations about "permanent" listing is very short and will require that the highest priority be attached to completion of that effort. The Commissioner believes that it is reasonable to expect that the same high priority will be given to this project by the petitioners. Final determinations on the provisionally listed colors can be made in a timely fashion only if demanding but realistic time requirements are imposed.

In the unlikely event that unforeseen and unavoidable circumstances arise to make compliance with the requirements of the final regulation virtually impossible, the Commissioner will consider requests for brief extensions of the closing dates. The Commissioner cautions, however, that such requests will be considered only if "extraordinary circumstances" exist and maximum effort has been given to meeting the deadlines.

The closing dates of July 1, 1977, September 30, 1977, and December 31, 1980, were proposed in § 8.505 (a), (b), (c), and (d) respectively, based on the Commissioner's expectation that the final regulation would be issued by December 31, 1976. Because of the unexpectedly lengthy time required to review the comments and the resulting delay in issuing this regulation, the closing dates established in § 8.505 (b), (c), and (d) have been extended for an additional 30 days. Thus, the closing dates in § 8.505 (b) and (c) will be October 31, 1977, and the closing dates in § 8.505(d) will be January 31, 1981. The closing date for the provisionally listed color additives that require eye-area studies under § 8.505(a) is retained at July 1, 1977, because those studies are underway and the petitioners have advised FDA that they can meet the proposed deadlines. Finally, all the deadlines imposed by § 8.505 have been computed from the date of publication of the final regulation in the FEDERAL REGISTER.

26. A requirement that progress reports be submitted to FDA on the chronic feeding studies required by § 8.505(d) was inadvertently omitted from the proposal. Section 8.505(d)(3) has been revised to require the submission to FDA of an initial progress report and further reports at 6-month intervals thereafter.

Having evaluated the comments and the data submitted with them, the Commissioner concludes that the extension of the closing dates for the provisionally listed color additives listed in § 8.501 subject to the conditions of § 8.505 is reasonable and in the public interest.

In accordance with the provisions of 5 U.S.C. 553 (d)(1) and (d)(3) this postponement is effective on January 31, 1977 so as to permit the uninterrupted use of the affected color additives.

Therefore, under the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86–618, 74 Stat. 404–407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)) Part 8 of Subchapter A of Title 21 of the Code of Federal Regulations is amended as follows:

1. By amending § 8.501 by revising the introductory text and the tables in paragraphs (a), (b), (c), (f) and (g) to read as follows:

§ 8.501 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 376 note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for such use. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), (c), (f), and (g) of this section are provisionally listed until the closing dates set forth therein, conditioned on compliance with the applicable requirements of paragraphs (a), (b), (c), and (d) of § 8.505.

(a) * * *

	Closing date		Restrictions
	Food use	Drug and cosmetic use	
FD&C Green No. 3 (§ 9.23 of this chapter)	Jan. 31, 1981	Jan. 31, 1981	
FD&C Yellow No. 5 (§ 8.275 of this chapter)	do.[1]	do.	
FD&C Yellow No. 6 (§ 9.41 of this chapter)	do.	do.	
FD&C Red No. 3 (§ 8.242 of this chapter)	do.[1]	do.	
FD&C Blue No. 1 (§ 8.206 of this chapter)	do.[1]	do.	
FD&C Blue No. 2 (§ 8.4022 of this chapter)	do.	do.	Food and ingested drugs.
Lakes (FD&C) (§ 9.100 of this chapter)			

[1] Lakes only.

(b) * * *

	Closing date	Restrictions
D&C Green No. 5 (sec. 8.4069 of this chapter)	Jan. 31, 1981	
D&C Green No. 6 (sec. 8.4070 (a) and (b) of this chapter)	do.	
D&C Yellow No. 10 (sec. 9.133 of this chapter)	do.	
D&C Red No. 6 (sec. 9.151 of this chapter)	do.	
D&C Red No. 7 (sec. 9.152 of this chapter)	do.	
D&C Red No. 8 (sec 9.153 of this chapter)	do.	Sec. 8.503.
D&C Red No. 9 (sec. 9.154 of this chapter)	do.	Do.
D&C Red No. 10 (sec. 9.155 of this chapter)	do.	Do.
D&C Red No. 11 (sec. 9.156 of this chapter)	do.	Do.
D&C Red No. 12 (sec. 9.157 of this chapter)	do.	Do.
D&C Red No. 13 (sec. 9.158 of this chapter)	do.	Do.
D&C Red No. 19 (sec. 9.164 of this chapter)	do.	Do.
D&C Red No. 21 (sec. 9.166 of this chapter)	do.	
D&C Red No. 22 (sec. 9.167 of this chapter)	do.	
D&C Red No. 27 (sec. 9.172 of this chapter)	Jan. 31, 1981	
D&C Red No. 28 (sec. 9.173 of this chapter)	do.	
D&C Red No. 30 (sec. 9.175 of this chapter)	do.	
D&C Red No. 33 (sec. 9.178 of this chapter)	do.	Sec. 8.503.
D&C Red No. 36 (sec. 9.181 of this chapter)	do.	Do.
D&C Red No. 37 (sec. 9.182 of this chapter)	do.	Do.
D&C Orange No. 4 (sec. 9.201 of this chapter)	Oct. 31, 1977	External use only.
D&C Orange No. 5 (sec. 9.202 of this chapter)	Jan. 31, 1981	Sec. 8.503.
D&C Orange No. 10 (sec. 9.207 of this chapter)	do.	
D&C Orange No. 11 (sec. 9.208 of this chapter)	do.	
D&C Orange No. 17 (sec. 9.214 of this chapter)	do.	Do.
D&C Blue No. 6 (sec. 9.242 of this chapter)	do.	
Lakes (D&C) (sec. 9.280 of this chapter)		

(c) * * *

	Closing date	Restrictions
Ext. D&C Yellow No. 1 (sec. 9.301 of this chapter)	Oct. 31, 1977	
Ext. D&C Green No. 1 (sec. 9.400 of this chapter)	do.	
Lakes (ext. D&C) (sec. 9.440 of this chapter)		

* * * * * * *

(f) * * *

	Closing date	Restrictions
Logwood	Oct. 31, 1977	Surgical suture use only.

(g) * * *

Color additive	Closing date	Restrictions
Aluminum powder	July 1, 1977	None.
Annatto	do.	Do.
Bismuth citrate	Oct. 31, 1977	For use as a color component in hair dye.
Bismuth oxychloride	do.	None.
Bronze powder	July 1, 1977	Do.
Caramel	Jan. 31, 1981	Do.
Carmine	July 1, 1977	Do.
Carotene	do.	Do.
Chromium hydroxide green	do.	Do.
Chromium oxide greens	do.	Do.
Copper, metallic powder	do.	Do.
Ferric ferrocyanide (iron blue)	do.	Do.
Graphite	Oct. 31, 1977	Do.
Guanine (pearl essence)	July 1, 1977	Do.
Lead acetate	Oct. 31, 1977	For use as a color component in hair dye.
Mica	July 1, 1977	None
Zinc oxide	do.	Do.

2. By adding new § 8.505 to read as follows:

§ 8.505 Conditions of provisional listing.

The closing dates for the use of the color additives provisionally listed in § 8.501 are postponed until the dates established in that section conditioned on compliance with the requirements of paragraphs (a), (b), (c), and (d) of this section, where applicable. The closing dates will not be postponed beyond the dates in § 8.501 unless extraordinary circumstances are shown. Requests for further postponement based on extraordinary circumstances shall be submitted in writing and state in detail the basis for the request. If the requirements of paragraphs (a), (b), (c), and (d) of this section are not complied with, the provisional listing for the color additive(s) involved will be terminated immediately.

(a) The closing date for the following 14 color additives is postponed until July 1, 1977, while 4-week eye area studies in the rabbit are conducted and evaluated, and subject to compliance with the requirements of this paragraph: Aluminum powder, annatto, bismuth oxychloride, bronze powder, caramel, carmine, carotene, chromium hydroxide green, chromium oxide greens, copper (metallic powder), ferric ferrocyanide, guanine (pearl essence), mica, and zinc oxide.

(1) At least one petitioner for each of the 14 color additives listed in paragraph (a) of this section shall agree in writing by March 7, 1977 to undertake the eye area studies.

(2) A full written report of the results of the studies shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, by March 21, 1977.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

(b) The closing date for bismuth citrate, bismuth oxychloride, caramel, and lead acetate is postponed until October 31, 1977, while short-term studies are conducted and evaluated, and subject to compliance with the requirements of this paragraph.

(1) At least one petitioner for each of of the four color additives listed in paragraph (b) of this section shall agree in writing by March 7, 1977 to undertake the short-term studies on the color additives.

(2) A full written report on the absorption studies for bismuth citrate and lead acetate and a full written report on the subchronic studies for bismuth citrate, bismuth oxychloride, and caramel shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, by August 3, 1977.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

(c) The closing date for the following nine color additives is postponed until October 31, 1977, while chemistry data and analytical methods to establish specifications for them are developed and evaluated and subject to compliance with the requirements of this paragraph: D&C Yellow No. 10, D&C Red No. 6, D&C Red No. 7, D&C Red No. 30, D&C Orange No. 4, D&C Blue No. 6, Ext. D&C Yellow No. 1, Ext. D&C Green No. 1, and graphite.

(1) At least one petitioner for each of the nine color additives listed in paragraph (c) of this section shall agree in writing by March 3, 1977 to undertake to develop the necessary chemistry data and analytical methods for the color additives.

(2) The required chemistry data and analytical methods shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, by August 3, 1977.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additive to cause adverse effects.

(d) The closing date for the following 32 color additives is postponed until January 31, 1981, while chronic toxicity feeding studies and in the case of caramel, a lifetime mouse skin painting study, are conducted and evaluated, and subject to compliance with the requirements of this paragraph: FD&C Yellow No. 5, FD&C Yellow No. 6, D&C Yellow No. 10, FD&C Red No. 3, D&C Red No. 6, D&C Red No. 7, D&C Red No. 8, D&C Red No. 9, D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, D&C Red No. 13, D&C Red No. 19, D&C Red No. 21, D&C Red No. 22, D&C Red No. 27, D&C Red No. 28, D&C Red No. 30, D&C Red No. 33, D&C Red No. 36, D&C Red No. 37, FD&C Green No. 3, D&C Green No. 5, D&C Green No. 6, FD&C Blue No. 1, FD&C Blue No. 2, D&C Blue No. 6, D&C Orange No. 5, D&C Orange No. 10, D&C Orange No. 11, D&C Orange No. 17, and caramel.

(1) At least one petitioner for each of the 32 color additives listed in paragraph (d) of this section shall agree in writing by March 7, 1977 to undertake the required studies on the color additives.

(2) The petitioners undertaking the studies shall submit a protocol for the conduct of the studies to the Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, for review, and acceptance or rejection, by April 5, 1977.

(3) An initial progress report of the studies on the color additives shall be submitted to the Division of Food and Color Additives by December 31, 1977. Further progress reports shall be submitted at 6-month intervals thereafter. A full report of the studies conducted on the color additives shall be submitted to the Division of Food and Color Additives by August 4, 1980.

(4) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate potential for the color additive to cause adverse effects.

Effective date: This regulation shall be effective January 31, 1977.

(Title II, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: January 31, 1977.

JOSEPH P. HILE,
Acting Commissioner of Food and Drugs.

[FR Doc.77-3362 Filed 1-31-77;12:03 pm]