IV. Commission's View of Value Based Disclosures

Notably, a possible exception to the Commission's expectation of acceptance of FASB standards in this area is the issue of value based disclosures for oil and gas reserves, such as the "Present Value of Estimated Future Net Revenues" as defined in Regulation S–X. In its deliberations to date the FASB has not required value based disclosure for oil and gas reserves, but as part of the proposed project, the Commission expects that the FASB will consider various types of value disclosures in its project. It may be appropriate to use a discount rate other than 10 percent or to use a set of discount rates, depending upon risk. A range of values rather than a point estimate may be considered. The above examples of items for consideration are not intended to be restrictive and the Commission expects that the FASB will exercise its own judgment in reviewing alternatives and arriving at its conclusions with respect to the value based disclosure issues and all other issues to be considered within the project's scope.

However, because the Commission believes value based disclosures are important, even if the FASB does not require value based disclosures for all oil and gas companies, the Commission will likely continue to require such disclosure from registrants. If that is the case, the public record generated by the FASB during its deliberations should be helpful in determining the appropriate basis for any value disclosure which the Commission may require in the future.

The Commission's strong commitment to value based disclosure should be distinguished, however, from its support of RRA as a supplemental measure of earnings. The Commission believes that RRA should be carefully considered for supplementary disclosure but it has no preconceived conclusions as to the outcome of such deliberations.

V. Other

In arriving at its conclusion that RRA is not feasible as uniform method of accounting in primary financial statements, the Commission has not readdressed the issue of a uniform method of accounting by oil and gas producers. Concepts developed by the FASB in its conceptual framework project will have an impact on the ultimate resolution of this question. Therefore, the Commission does not intend to attempt to resolve that issue until after it considers the results of the FASB's conceptual framework efforts.

The Commission has reviewed its responsibility under the Energy Policy and Conservation Act of 1975, 89 Stat. 871 ("EPCA"), which directed the Commission to assure the development and observance of accounting practices to be followed in the preparation of accounts by oil and gas producers. It has determined that the announcements and course of action outlined in this release are not inconsistent with its responsibilities under EPCA. However, after the FASB has developed its comprehensive disclosure package, the Commission will separately consider any necessary rule making action under the securities laws and whether any EPCA rule making is necessary to assure the availability of such information to the Department of Energy.

By the Commission.

George A. Fitzsimmons,

Secretary.

February 26, 1981.

[FR Doc. 81–7114; Filed 3–5–81; 8:45 am]

BILLING CODE 8010–01–M

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17 CFR Part 240

[Release Nos. 33–6292; 34–17556; IC–11633]

Application of Rule 10b–6 to Certain Distributions of Securities by Issuers

Correction

In FR Doc. 81–6908 appearing on page 15133 in the issue of Wednesday, March 4, 1981, on page 15134, first column, § 240.10b–6, the paragraph designated "(5)" should read "(e)".

BILLING CODE 1505–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 282

[Docket No. RM79–21]

Alternative Fuel Price Ceilings for Incremental Pricing Under the Natural Gas Policy Act of 1978

AGENCY: Federal Energy Regulatory Commission.

ACTION: Interim Rule.

SUMMARY: The Commission revises on an interim basis the methodology for calculating the monthly alternative fuel price ceilings for state regions. Under the revised methodology, the applicable alternative fuel price ceiling published on the twentieth of each month for each of the contiguous states shall be the lower of the alternative fuel price ceiling for the state or the alternative fuel price ceiling for the multistate region in which the state is located. In addition, § 282.404(a) of the Commission's regulations is amended by adding subparagraph (4) making effective March 1981 prices that were changed as a result of the newly revised methodology. Such prices supersede those corresponding state prices published on February 20, 1981.

DATES: Effective March 2, 1981.

Written comments by April 13, 1981. Requests for oral hearing by March 13, 1981.

ADDRESS: Office of Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, Reference Docket No. RM79–21.

FOR FURTHER INFORMATION CONTACT:

Thomas P. Gross, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, (202) 357–8171.

Sandra Delude, Office of Pipeline and Producer Regulation, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, (202) 357–5522.

Interim Rule

Issued: March 2, 1981.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is amending, on an interim basis, its regulations on incremental pricing (18 CFR Part 282) under Title II of the Natural Gas Policy Act of 1978 (NGPA) (15 U.S.C. 3301–3432). Specifically, § 282.404(a) is amended by adding subparagraph (4) to provide that the alternative fuel price ceilings for March 1981, listed in new § 282.404(a)(4), supersede the corresponding state ceilings published on February 20, 1981. In addition, this order provides that the alternative fuel price ceilings published on the twentieth of each month following February 1981, for each of the 48 lower contiguous states shall be the lower of:

(1) the alternative fuel price ceiling applicable to the state; or

(2) the alternative fuel price ceiling applicable to the multistate region in which the state is located.

II. Background

Title II of the NGPA requires the Commission to prescribe and make effective a program of incremental pricing of natural gas which is used as industrial boiler fuel. Section 204(e) of the NGPA directs the Commission to establish ceilings on gas prices charged

to incrementally priced users, based on the cost of alternative fuel oils in each region designated by the Commission.

The Commission's current regulations implementing the incremental pricing program establish two sets of regions: (1) 48 regions, each region being one of the 48 contiguous states; and (2) eight multistate regions, labeled Regions A through H. The 48 state regions are used to calculate alternative fuel price ceilings which are published each month in the **Federal Register** on or before the twentieth day of the month preceding their effective date. In addition as provided in Appendix I to Subpart D of Part 282, the multistate regions may be used by the Commission in deriving alternative fuel price ceilings for state incremental pricing regions (1) for which statistically valid samples of oil prices may be unavailable, or (2) where the Commission determines that the public interest requires use of the regional ceiling in place of the state ceiling. The price ceiling for each region (state or multistate) is calculated by a formula which uses the price of high-sulfur No. 6 fuel oil observed in that region during a previous period. The collection of data, the application of the formula, and the publication of the ceilings are performed by the Energy Information Administration (EIA) in accordance with Commission direction.

The Commission recently instituted a rulemaking proceeding in Docket No. RM79–21 for the purpose of re-examining both the designation of the incremental pricing regions and the methodology for calculating the price ceilings in those regions. On November 4, 1980, a Notice of Inquiry was issued in this docket (45 FR 74505, November 10, 1980), requesting public comment on possible revisions to the current regions and methodology. More than 50 written comments were filed. In addition, members of the public were given an opportunity to discuss the Notice of Inquiry in informal technical conferences held in Kansas City, Missouri, on November 21, 1980 and in Washington, D.C., on November 24, 1980, and January 6, 1981.

III. Discussion

Studies made by the Commission staff demonstrate that substantial pricing disparities exist in the price ceilings for neighboring states and that the impact of such disparities is increasing as the cost of high-sulfur No. 6 fuel oil rises.[1] The disparities may be due to actual oil price differences in neighboring states, too few oil transactions, or some other factor or combination of factors. (The EIA is continuing to study the methodology for calculating the price ceilings program in an attempt to discern the reason for the disparities.)

As the Commission noted in the Notice of Inquiry, these disparities increase the possibility of industrial users' switching from natural gas to fuel oil purchased in a nearby state. In addition, substantial pricing disparities create inequities, in that industrial gas users in different states, but within the same marketing area, may pay substantially different prices for natural gas. As a result, the Commission has determined to issue an interim rule amending the existing methodology in order to discourage potential fuel switching.

Written and oral comments submitted in response to the Notice of Inquiry generally indicated that the current alternative fuel price ceilings are working as well as possible and that many of the changes discussed in the Commission's Notice of Inquiry would only aggravate existing problems and inject uncertainty and instability into the Commission's current incremental pricing program. The commenters urged the Commission to retain the basic regulatory structure now in effect, but to add some flexibility to the methodology to correct price ceilings which do not accurately reflect current market prices.

One of the most commonly proposed additions to the current methodology was a fail-safe mechanism under which a non-exempt user of natural gas could reduce the applicable incremental pricing surcharge to a lower alternative fuel price if the user could certify to the Commission that the lower alternative fuel price is available to the facility.

Other comments proposed alternative mechanisms, such as the "contiguous state approach" or the multistate regional approach." Under the contiguous state approach, the price ceiling would be the lowest price ceiling in any state contiguous to the state in question if lower than the otherwise applicable state price ceiling. Under the multistate regional approach, the price ceiling would be the lower of the price ceiling applicable to the mutistate region in which the state is located, or the alternative fuel price ceiling which would otherwise be applicable to the state.

The Commission agrees that some flexibility should be added to the current methodology. The Commission has considered the fail-safe mechanism in some detail during the initial implementaton of the incremental pricing program and in conjunction with this rulemaking. It believes that such a mechanism would be difficult to implement at this time. As proposed in the comments, the price ceiling in a facility-by-facility fail-safe mechanism is subject to potential manipulation. Administrative problems also exist with respect to verification of the availability of a lower price and correction. If the price certified is found to be incorrect. The contiguous state approach, while providing flexibility, would raise issues relating to an appropriate definition of "contiguous." However, the multistate regional approach would provide the needed flexibility without presenting either the definitional problems of the contiguous state approach or the administrative problems of the fail-safe mechanism. Accordingly, the Commission is adopting the multistate regional approach in this rulemaking. The implementation of the multistate regional approach will result in some, but not a large, reduction in total MSAC's (maximum surcharge absorption capability).[2] However, the Commission believes that the reduction is outweighed by the benefits provided by increased flexibility and improved accuracy in the price ceilings.

Specifically, the methodology for calculating the altenative fuel price ceilings is revised to provide that the alternative fuel price ceilings for each of the 48 contiguous states shall be the lower of (1) the alternative fuel price ceiling applicable to the state, or (2) the alternative fuel price ceiling applicable to the multistate region in which the state is located.

Three other proposals which were discussed in the Notice of Inquiry were, (1) the grouping of No. 2 and No. 6 fuel oil prices, (2) the cumulative decrement approach, and (3) sixteen proposed multistate regions. Virtually all of the comments opposed the first two proposals, and the Commission declines to adopt either of these methods as more practicable than the system already in effect. The comments were divided, however, as to whether the Commission should adopt the sixteen proposed regions or retain the current 48 state and eight multistate regions. None of the

[1] *See*, Rule Adopting Revised Alternative Fuel Price Ceilings for the State of Kentucky, Docket No. RM81–9, issued December 24, 1980 (46 FR 2036).

[2] The exact amount of MSAC reduction is difficult, if not impossible, to quantify. The Commission has analyzed prices in the nine states (Pennsylvania, Georgia, California, Illinois, Indiana, Michigan, New Jersey, New York and Ohio) which contain approximately two-thirds of all facilities subject to incremental pricing. For the five-month period of October 1, 1980, through February, 1981, seventeen of the forty-five published prices would have been reduced had the rule adopted herein been in effect. The amounts involved are noticeable, but do not appear to be of a magnitude that would outweigh the advantages of this adjustment.

comments offered any compelling reasons to adopt the sixteen-region approach. Therefore, rather than subject the current methodology to additional confusion and uncertainty, the Commission has decided to retain the existing 48 state and eight multistate regions at this time.

The Commission also recognizes that certain individual or state-wide circumstances may exist in which some type of relief or adjustment from the methodology adopted in this rule may be appropriate. The Commission will continue to review any such situations on a case-by-case basis and to administer relief, where appropriate, by means of staff adjustments pursuant to section 502(c) of the NGPA or by rulemaking.

The Commission also notes that the EIA continues to study various methodologies which may eventually prove to be useful in calculating appropriate alternative fuel price ceilings. The Commission has been informed that one such methodology has shown promise and is currently being evaluated. When detailed information and data on this method become available from the EIA, the Commission will consider such material.

IV. Summary of the Interim Rule

As discussed above, the Commission has determined that the alternative fuel price ceiling for each of the 48 contiguous state regions should be the lower of either the ceiling calculated for that state or the ceiling calculated for the multistate region in which the state is located. In order to implement this decision for the month of March 1981, for which alternative fuel price ceilings were published on February 20, 1981, the Commission is amending § 282.404(a) of its regulations by adding new subparagraph (4). Subparagraph (4) lists the ceilings for March 1981 which shall supersede those previously published on February 20, 1981; that is, it lists the appropriate multistate regional ceilings for each state in which the multistate regional ceiling for March 1981, is lower than the state regional ceiling. To implement this methodology for months following March 1981, the Commission is directing its Executive Director to direct EIA to publish as the alternative fuel price ceilings applicable to each state region for months following March 1981, the lower of either the ceiling calculated for that state or the ceiling calculated for the multistate region in which the state is located.

V. Effective Date

The Commission believes that this rule will promote equity and discourage potential fuel switching. Accordingly, the Commission finds that good cause exists in accordance with 5 U.S.C. 553 (b) and (d) to make this rule effective immediately as an interim rule, applicable to all alternative fuel price ceilings for the month of March 1981, and thereafter, until the Commission issues a final rule in this docket. The Commission will afford an opportunity for interested persons to present views and comments, as set forth below.

VI. Comment Procedures

A. *Written Comments.* Interested persons are invited to submit written comments, data, views, or arguments with respect to this interim rule. Comments should be submitted to the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, and should reference Docket No. RM79–21. An original and 14 copies should be filed. All comments received prior to 4:30 p.m. EST, April 13, 1981, will be considered by the Commission prior to promulgation of final regulations. All written submissions will be placed in the public file which has been established in this docket and which is available for public inspection through the Commission's Division of Public Information, Room 100, 825 North Capitol Street, NE., Washington, D.C., during regular business hours.

B. *Public Hearing.* Interested persons may request the opportunity for an oral presentation of their views at a public hearing. Requests for an oral hearing should be submitted no later than March 13, 1981, to the Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, and should reference Docket No. RM79–21. If any requests are received by that time, the hearing will be held on March 23, 1981, at the above address, and will be announced by March 18, 1981.

(Natural Gas Policy Act of 1978, 15 U.S.C. 3301 *et seq.*; Department of Energy Organization Act, 42 U.S.C. 7101 *et seq.*; E.O. 12009, 42 CFR 46267 (1978))

In consideration of the foregoing, the Commission amends Subpart D, Part 282, Subchapter I, of Chapter I, Title 18 of the Code of Federal Regulations, on an interim basis, as provided below, effective upon issuance.

By the Commission.

Kenneth F. Plumb,

Secretary.

Section 282.404 is amended in paragraph (a) by adding subparagraph (4) to read as follows:

§ 282.404 Alternative fuel price ceilings.

(a) *General rule.*

* * * * *

(4) for the month of March, 1981, the following state ceilings shall be effective and shall supersede the corresponding state ceilings published on February 20, 1981:

State	Dollars per million Btu's
Arkansas	3.70
California	3.44
Delaware	4.23
Idaho	3.76
Indiana	3.54
Iowa	4.03
Kansas	4.03
Louisiana	3.70
Maryland	4.23
Michigan	3.54
New Hampshire	4.92
New Jersey	4.23
North Carolina	4.50
North Dakota	4.03
Ohio	3.54
Oklahoma	3.70
Oregon	3.44
Pennsylvania	4.23
South Carolina	4.50
South Dakota	4.03
Utah	3.76
Vermont	4.92
Virginia	4.50
West Virginia	3.54

* * * * *

[FR Doc. 81-7220 Filed 3-5-81; 8:45 am]

BILLING CODE 6450-85-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 81

[Docket No. 80N-0447]

Removal of Stay of Regulation for the Listing of Lead Acetate as a Color Additive in Cosmetics That Color the Hair on the Scalp; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Removal of Stay and Confirmation of Effective Date.

SUMMARY: The Food and Drug Administration (FDA) is removing the stay of regulation for the permanent listing of lead acetate for use as a color additive in cosmetics that color the hair on the scalp. The regulation was stayed by the filing of objections under the formal rulemaking provisions of the Federal Food, Drug, and Cosmetic Act. FDA received no requests for hearing in response to the regulation. The stay remained in effect while FDA evaluated

and acted on the objections. The agency has now completed its evaluation of the objections and concludes that they are not adequate to continue the stay of the regulation listing lead acetate as a color additive. Therefore, this document removes the stay of the regulation and confirms the effective date of December 1, 1980, for the regulation listing lead acetate as a color additive. This document also amends the color additive regulations by removing lead acetate from the color additive provisional list.

EFFECTIVE DATE: March 3, 1981.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: The current closing date of March 3, 1981, for the color additive provisional listing of lead acetate was established by a final regulation which was published in the **Federal Register** of December 30, 1980 (45 FR 85725). The date was set to provide FDA time to evaluate and act on objections received in response to a final regulation that was published in the **Federal Register** of October 31, 1980 (45 FR 72112) and that approved a petition for the permanent listing of lead acetate. The preamble to the December 30, 1980, rule announced that the regulation which permanently lists lead acetate was stayed pending final agency action on the objections (45 FR 85725). No requests for a hearing, however, were received in response to the permanent listing regulation.

After evaluating the objections received, the agency finds that none of them presents a genuine and substantial issue of fact which warrants a hearing (see 21 CFR 12.24(b)).

The agency has received four letters stating objections to the permanent listing regulation for lead acetate. One objection was received from an individual; a joint objection was received from two consumer groups; and two separate objection letters were received from two medical associations. The letters are on file in the Dockets Management Branch in this docket, 80N–0447. The objections and the agency's responses to them are summarized below.

1. The objection filed jointly by two consumer groups stated an opposition "to the FDA's action permanently listing lead acetate for use in hair dyes on the grounds that the FDA has no authority to approve for use as a color additive any substance which the Agency has found causes cancer in man or animals." The objectors contend that FDA is required by the Delaney Clause to deny the petition to list premanently lead acetate because the policy embodied in the clause is an absolute prohibition on the approval of any additive that causes cancer in man or animals.

For the scientific and legal reasons which were fully explained in the October 31, 1980, listing regulation, the agency disagrees with the narrow legal interpretation of the Color Additive Amendments of 1960, 21 U.S.C. 376, note, set forth in this objection. Because of the detailed discussion of the scientific facts relative to lead acetate hair dyes and the legal standards applicable to the permanent listing of a noningested color additive in the preamble to the October 31, 1980, final rule, further explication here would serve no useful purpose. Thus, FDA incorporates by reference herein all scientific, legal, and policy positions set forth in the preamble to the October 31, 1980, final rule. These positions support the agency's conclusion that lead acetate, under any reasonable standard, is safe and that the Delaney clause does not bar the permanent listing of this color additive for use in hair dyes that color the hair on the scalp.

2. The consumer groups also objected to FDA's risk assessment that was performed using "worst case estimates" and to the analysis of toxicity data on lead acetate showing, in the agency's opinion, that if any risk does exist, it is clearly insignificant and presents no public health or safety concerns. The objection stated "if the risk is 1 in a million and if more than 1 million persons use hair dyes with lead acetate, then at least 1 person will die as a direct consequence of the FDA's decision." This conclusion reflects a misunderstanding of the risk estimation that FDA performed, and of the meaning and use of risk estimates in determining whether a substance is safe.

In the preamble to the October 31, 1980, final regulation, the agency reported a calculation that the upper limit of lifetime cancer risk from the use of lead acetate in hair dyes was approximately 2 in 10 million lifetimes (i.e., 1 in 5 million lifetimes). Upper limit estimates of risk using "worst case" assumptions cannot be used to predict with mathematical precision what will actually occur. Yet, because risk estimates take into account the risk resulting from incomplete information, extreme assumptions of overuse, abuse, and over application, etc., (hence, "worst case estimates"), are factored in to reach a conclusion with reasonable certainty of what will not occur. The agency's conclusion that less than 1 out of 5 million persons would be at risk from the use of this color additive in hair dyes based upon the "worst case estimates" is consistent with the likelihood that no cancers will result from the topical use of this color additive. Thus, in terms of the public health protection, this additive presents no significant safety or health concerns and is, therefore, safe. However, a risk assessment demonstrating that 1 in 5 million persons may be at risk is totally inconsistent with the objection's statement that at least 1 person will die as a direct consequence. Therefore, the agency disagrees with this aspect of the objection and concludes that it has no merit.

3. Three of the objections received focused on certain issues regarding human lead exposure. The objections emphasized that lead is a highly toxic compound and that, at certain levels of exposure, lead can cause poisoning in children and adults. The objections shared the view that the use of lead acetate in hair dyes would contribute significantly to the lead exposure of users of the dyes. Some of the objections expressed a concern that the approval of lead acetate signals a change in FDA's regulatory policies toward human exposure to lead from "minor" environmental sources. The objections also contended that although human exposure to lead from lead acetate may be small, each source of lead exposure adds to the body burden and should be prohibited wherever possible.

The agency recognizes and agrees with the objections that certain levels of lead exposure can result in toxic manifestations in humans and that, because of this toxicity, human exposure to lead should be reduced. The agency's position on lead was summarized in an advance notice of proposed rulemaking on lead in the food supply that was published in the **Federal Register** of August 31, 1979 (44 FR 51233). That notice cited several comprehensive reports regarding different aspects of lead toxicity that serve as partial basis for the agency's regulatory position concerning lead. However, the levels of lead associated with toxic effects from the sources discussed in the advance notice of proposed rulemaking are quite different from the levels associated with use of lead acetate hair dyes.

The agency has completed a comprehensive review and evaluation of data relevant to the color additive petition for lead acetate used in hair dyes. This review included consideration of the potential and actual toxicity of lead. On the basis of these

data, which included tests demonstrating an almost infinitesimally low absorption of lead from lead acetate hair dyes, the agency concludes that the use of lead acetate is safe in that it represents no reasonable prospect of harm and that its contribution to the total body burden is inconsequentially small. This conclusion is a reaffirmation of the safety of lead acetate in terms of toxic effect set forth in the **Federal Register** of March 6, 1979 (44 FR 12206) and October 31, 1980 (45 FR 72114). The agency advises that the objections regarding the toxicity of lead that were received did not provide any new scientific information of a type that has not been previously considered. Therefore, the agency concludes that data describing the toxic effects of elevated levels of lead in the body are not relevant to the issue of safety of lead acetate hair dye where there will be no perceptible elevations in body lead levels from its use.

The agency also advises that the permanent listing of lead acetate as a color additive does not represent a change in the overall agency regulatory policy concerning lead. This action represents only a clearance for a color additive found to be safe under its limited conditions of use. The agency will continue to apply its regulatory authority to reduce lead contamination in other substances that are subject to the Federal Food, Drug, and Cosmetic Act.

4. An objection from a medical association suggested that the agency consider a scientific article that was published in the *Lancet* of January 10, 1970 on the effects of lead inhibition of *delta*-aminolevulinic acid dehydrogenase (*delta*-ALAD), an enzyme involved in the synthesis of heme. The objection summarized the article by stating "* * * delta-aminolevulinic acid dehydrogenase, is inhibited at very low levels, down to less than 10 parts per million, far below the blood concentration considered to be dangerous by governmental agencies."

FDA had previously considered this scientific information as part of its general review of the effects of human lead exposure. These data show an inhibition of *delta*-ALAD at blood levels as low as 10 micrograms per 100 milliliters of blood, or, in fact, 0.1 part per million of lead in the blood, and not 10 parts per million as stated by the author. From review of the scientific literature, the agency recognizes that a blood-lead level of 10 to 20 micrograms per 100 milliliters is considered by the scientific community to be within the normal range for the general population. Although there may be some inhibition of *delta*-ALAD activity at these blood-lead levels, the health impact of these observations remains to be established, because normal heme synthesis is apparently not impaired.

The agency does not believe that the information presented in this objection with respect to *delta*-ALAD inhibition is relevant to the issue of lead acetate in hair dyes because the documented levels of absorption of lead from hair dye are far below those levels of lead absorption that would represent toxicological concern.

5. The objection further contended that it would be a serious mistake to assume that any additional amount of lead, even a small amount, is safe. In support of this conclusion, the objection stated that there is abundant evidence published in numerous scientific journals to justify a conclusion that "* * * many, if not the majority, of inhabitants in our country already suffer with subclinical symptoms of lead toxicity."

The agency does not agree that there is sufficient definitive evidence to justify those conclusions regarding low levels of lead exposure and presumed resultant lead toxicity. The agency remains concerned and aware of the toxicological significance of human exposure to lead and the possibility that toxic manifestations may occur at lower threshold levels than are currently associated with clinically confirmed lead poisoning. Because of this concern, the agency has encouraged the scientific community to provide new information and scientific data in this important area (see 44 FR 12205, March 6, 1979; and 44 FR 51223, August 31, 1979). The agency will continue to reevaluate its position regarding the overall human exposure to lead on the basis of the new information, when and if it is received.

6. The same objection concluded that "it is difficult to believe that a consumer protection agency of the Federal government would accept a study and conclusions by the very industry which profits from this poisonous substance." The objection also criticized FDA for not relying upon an absorption study performed by an independent laboratory rather than the sponsor of the color additive.

Under the Color Additive Amendments of 1960, 21 U.S.C. 376, note, the primary responsibility for conducting (as distinct from evaluating) studies to support the approval of color additive petitions filed with FDA lies with the sponsors of those petitions. Combe, Inc., a member of the petitioner for the permanent listing of lead acetate, Committee of the Progressive Hair Dye Industry, sponsored that particular radioactive lead skin absorption study that was evaluated by the agency and was used by the agency to determine that lead acetate in hair dyes is indeed absorbed through human skin, but in a miniscule amount. The agency advises that FDA personnel reviewed the experimental design, the overall facilities, and the sophisticated analytical procedures used before the actual study, as well as the final results of the study. The study was conducted by qualified scientists at the University of Glasgow. The agency can find no basis for challenging the professional competence of these scientists and concludes that the results of the study are appropriate and germane to the issue.

7. An objection from a second medical association was written in response to a United Press International press release concerning FDA's approval of lead acetate. This letter contained specific objections that were based, in part, on unspecified data or referred to scientific reports that were not submitted with the objection letter.

The agency advises that the conclusions that can be properly drawn from scientific studies depend upon the quality of those studies and the relevance of the studies to the issue in question. The agency has completed a comprehensive review of the scientific literature regarding lead toxicity and is not aware of any relevant scientific study concerning the issue of lead acetate in hair dyes that has not been considered. Moreover, FDA has also requested the submission of data relevant to lead acetate hair dyes through the rulemaking process (see 43 FR 8792; March 3, 1978, with respect to lead acetate; and 44 FR 12204; March 6, 1979, with respect to lead generally). On the basis of all available data the agency has concluded that lead acetate is safe in cosmetic hair dyes when used under specified conditions. Therefore, the agency cannot consider reversing a thoroughly considered decision without the receipt and evaluation of reports that it may not have considered previously.

8. The objection also criticized FDA's decision to list lead acetate because it "appears to be in complete contradiction to the duty which Congress has outlined" for FDA which has always involved carefully considering "potential benefits versus potential risks for the products used by the American consumer." It is further asserted that benefits from the use of lead acetate in products are "only cosmetic, while the

risks are substantial and clearly identifiable, and include serious potential biologic harm to the body."

The agency advises that its role under the Color Additive Amendments of 1960, 21 U.S.C. 376, note, is strictly limited. The agency is not permitted under the law to make value judgments about whether color additives are beneficial. Rather, the agency is only authorized to evaluate the data submitted in support of color additive petitions and to approve their use in food, drugs, cosmetics, and devices if the data show them to be safe; that is, the data establish with reasonable certainty that no harm will result from the intended use of the color additive (see H.R. Rept. No. 7624, 86th Cong., 2d Sess., p. 776 (1960); 21 CFR 70.3(i)).

9. In addition, the same objection alleged that data from unreported tests using "Hair Mineral Analysis" and "other parameters for determining increased body burden of lead" indicated that lead acetate applied for a prolonged interval of time (6 months to 2 years) resulted in elevations of lead in certain individuals. In addition, the objection cited the use of a testing procedure which included the "analysis of pubic as well as axillary hair. This procedure has been described in *Current Problems of Dermatology* by Drs. Marzulli, Watlington, and Maibach." The objection also stated that "provocative chelation" techniques indicate elevated lead levels in certain individuals from the use of lead hair dyes.

With respect to the "unreported tests," the agency advises that because no data supporting these observations have been submitted it cannot comment on whether those tests were scientifically valid or on whether any conclusions which might be drawn from them are relevant to this rulemaking. However, the agency has previously reviewed the cited study by Marzulli, Watlington, and Maibach:

> * * * Marzulli et al. reported in their study that there was an increase in the levels of lead in pubic and axillary hair after the administration of a lead acetate hair color to the hair of the scalp. They concluded that this might indicate lead was absorbed through the skin of the scalp and then deposited in the growing hair of the axillary and pubic regions. No blood or urine measurements of lead absorption were made, however, nor were there measures taken to rule out exogenous deposition, a necessary precaution according to Baloh. Generally, blood and urine levels are considered reliable indicators of systemic exposure to lead; lead levels in axillary and pubic hair are not generally considered reliable indicators of systemic uptake.
>
> The failure to measure blood or urine levels of lead in the subjects and the distinct possibility of exogenous deposition are significant shortcomings in this study and preclude reliance on it to draw any conclusions about the likelihood of lead absorption in humans (43 FR 8792; March 3, 1978).

The shortcomings of the study by Marzulli et al. and other earlier absorption studies necessitated an additional study using a particularly sensitive analytical methodology, the radioactive lead tracer technique, to resolve the issue of percutaneous absorption of lead acetate when used as a hair color. The agency believes that the radioactive tracer study provides the most reliable information regarding absorption.

10. The same objection concluded that there is a "significant risk from any additional lead" absorption. This conclusion is based upon several scientific articles and a book concerning toxicity that results from human lead exposure. The articles include: research papers published in the *New England Journal of Medicine* and *Science* by Dr. Clair Patterson, et al., regarding potential dangers from low-level lead exposures; a report from the National Academy of Sciences entitled "Lead in the Human Environment"; a research paper by Dr. Clair Patterson, et al., regarding potential dangers from low-level lead exposures; a report from the National Academy of Sciences entitled "Lead in the Human Environment"; and a research paper by Dr. H. Needleman that published in the *New England Journal of Medicine* regarding the impaired learning in classroom activity of students with elevated lead levels. Also cited was a report published by A. Schausss in the book "Diet, Crime, and Delinquency" that deals with criminal activity of persons having a high probability of showing elevated levels of heavy metals in their hair. In addition, this objection also cites an unidentified epidemiological study published in Switzerland that is believed by the objector to demonstrate an association between lead exposure and "adverse effects on the immune system as well as the potential mutagenicity and/or carcinogenicity of lead." This report, however, was not submitted to the agency for consideration and evaluation.

The agency is aware of the research being conducted regarding the toxic manifestations of lead exposure. Indeed, the report by the National Academy of Sciences and the research published by Drs. Patterson and Needleman have been reviewed by the agency. However, because these studies concern lead exposure levels far above those levels associated with lead hair dye use, the agency does not believe that this information is relevant to whether lead acetate should be allowed for use as a color additive in hair dyes. There is no evidence to suggest that the slight additional amount of lead absorbed from the use of led acetate hair dye (i.e., approximately 0.5 microgram (μg) per application) will increase an adult's risk of lead-induced neuropathy or other adverse health effects. Also, several of the studies cited as relevant to the issue of the safety of lead acetate hair dyes were studies on the effects of elevated lead levels in children. Because lead acetate hair dyes are not used and not intended for use in children, it cannot be considered as a potential contributing factor in elevated lead levels in children.

The agency notes that this objection has misinterpreted the amount of lead that may be absorbed through the scalp skin due to the use of lead acetate in hair dyes. The objection appeared to confuse the absolute amount of lead absorbed by a person, one half μg per application, with a purported concentration of lead in some unspecified medium (presumably blood) of one half part per million (0.5 ppm). Because the use of lead acetate hair dye would not result in a blood concentration level of 0.5 ppm, and in the absence of any other information, it appears that the objection was based on an incorrect interpretation of the data.

11. The remaining objection was submitted by an individual who asserted that the listing regulation for lead acetate ignored the mercury content and permitted lead far in excess of that permitted in other products not intended for topical application, such as paint and "decorative glassware."

The agency notes that the objection also misinterpreted the lead acetate absorption level in claiming that 0.5 ppm lead would be absorbed per application. As noted in paragraph 10 above, the figure 0.5 ppm is an error and does not represent the documented level of absorption (0.5 μg) expected from hair dye use. The objection also stated that an experience with grey hair dye restorers has shown them to contain several parts per million of mercury. The regulation listing lead acetate as a color additive restricts the mercury level in lead acetate to not more than 1 ppm in the color additive. The level of mercury (less than 1 ppm) in the color additive would be further diluted when added to the other hair dye materials so that a level of not more than 6 parts per billion of mercury would be expected in the finished hair dye product.

Conclusion

The agency has completed its evaluation of the objections and concludes, for the reasons discussed in this document, that the objections are not adequate to continue the stay of the regulations listing lead acetate as a color additive. No requests for a hearing were received in response to the listing regulation. Therefore, this document removes the stay of the regulation and confirms the effective date of December 1, 1980, for the regulation listing lead acetate as a color additive. With the listing of lead acetate the entries for lead acetate under Part 81 are now obsolete.

Therefore, the agency also concludes that the entries for "lead acetate" should be removed from Part 81, §§ 81.1 and 81.27 (21 CFR 81.1 and 81.27). The agency concludes that there is good cause not to provide for further public comment on this change in the regulation. The change is a mere editorial revision to delete lead acetate from the provisional list, due to the March 3, 1981, expiration of the closing date for provisional listing and due to this document conforming the effective date of the permanent listing regulation, rather than a substantive amendment.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)) and the Transitional Provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note)), and under authority delegated to the commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

§ 73.2396 [Stay terminated]

1. Part 73 is amended in Subpart C by terminating the stay which published in the **Federal Register** of December 30, 1980 (45 FR 85725) for § 73.2396 *Lead acetate.*

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

2. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives* in paragraph (g) by terminating the stay which published in the **Federal Register** of December 30, 1980 (45 FR 85725) and removing the entry "Lead acetate."

§ 81.27 [Amended]

b. In § 81.27 *Conditions of provisional listing* in paragraph (b) by removing the phrase "and for lead acetate until March 3, 1981, while a short-term skin penetration study is conducted and evaluated."

Effective date. These amendments become effective on March 3, 1981.

(Sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: February 27, 1981.

Mark Novitch,

Acting Commissioner of Food and Drugs.

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DEPARTMENT OF STATE

22 CFR Part 41

[Departmental Regulation 108.802]

Validity, Termination, and Replacement of Visa

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State amends its regulations relating to the validity, termination, and replacement of visa. Increasing numbers of nonimmigrant aliens have been presenting at the time of their applications for admission visas which have been physically removed from passports issued to them earlier and affixed to subsequently issued passports. In many instances, there is no method by which immigration inspectors at ports-of-entry can identify the applicant for admission as the alien to whom the visa was issued. These amendments provide that a visa that has been physically removed from the passport in which it was originally issued is invalid and is to be physically canceled by a consular or immigration officer to whom it is presented.

EFFECTIVE DATE: March 6, 1981.

FOR FURTHER INFORMATION CONTACT: Gerald M. Brown, Chief, Legislation and Regulations Division, Bureau of Consular Affairs, (202) 632–1900.

SUPPLEMENTARY INFORMATION: On September 8, 1980, the Department of State published proposed regulations in the **Federal Register** (45 FR 59175) that would include any nonimmigrant visa, physically removed from the passport in which it was originally issued, within the category of nonimmigrant visas whose validity can be terminated by a consular or immigration officer.

Two comments were received concerning the proposed regulations. One suggestion provided for the invalidation of a visa, which had been physically removed from a passport, only if the alien presenting such visa at a port of entry could not establish an identity as the person to whom the visa was issued. A conditional invalidation of this type would impose an onerous burden upon the carriers who are subject to monetary penalties prescribed by law for bringing any alien to the United States who is not in possession of a valid visa.

The other recommendation substituted for the proposed regulations a procedure which would preclude issuance of a nonimmigrant visa with a validity beyond the expiration date of the passport in which it was issued, if the government issuing the passport is known to have a policy of retaining expired passports. The suggested revision would not resolve the problem inherent in the surrender to these issuing authorities of substantial numbers of valid passports with no remaining blank pages on which visas can be stamped. Neither recommendation is acceptable as an alternative to the proposed regulations and therefore the regulations are adopted as proposed.

Dated: February 5, 1981.

Diego C. Asencio,

Assistant Secretary for Consular Affairs.

1. In § 41.122(e) the word "or" in subparagraph (6) is removed; the period at the end of subparagraph (7) is substituted by a semicolon followed by the word "or" and a new subparagraph (8) is added to read:

§ 41.122 Validity, termination and replacement of visa.

* * * * *

(e) *Termination of validity by consular or immigration officer.* * * *

(8) The visa has been physically removed from the passport in which it was originally issued.

* * * * *

2. In § 41.122(f) subparagraph (1), after "United States," the phrase "the visa has been physically removed from the passport in which it was originally issued, or" is inserted.

3. In § 41.122(f) subparagraph (2) is revised to read:

§ 41.122 Validity, termination and replacement of visa.

* * * * *

(f) *Termination of validity prior to alien's journey to the United States.* * * *