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Food	Limitation (parts per mil- lion)	Use
Pink beans (cooked canned).	165	Promote color retention.
Red beans (cooked canned).	165	Promote color retention.

Dated: September 29, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-24587 Filed 10-6-93; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Serum Gonadotropin and Chorionic Gonadotropin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for the use of freeze dried serum gonadotropin and chorionic gonadotropin (P.G. 600®) to be reconstituted for subcutaneous injection for induction of estrus in healthy weaned sows experiencing delayed return to estrus.

EFFECTIVE DATE: October 7, 1993.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20857, 301-594-1602.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed supplemental NADA 140-856 that provides for the use of freeze dried serum gonadotropin and chorionic gonadotropin (P.G. 600®) to be reconstituted for subcutaneous injection for induction of estrus in healthy weaned sows experiencing delayed return to estrus. The supplemental NADA is approved as of August 30, 1993, and the regulations are amended in 21 CFR 522.1079(c) to reflect the approval. The basis for

approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food producing animals qualifies for 3 years of marketing exclusivity beginning on August 30, 1993, because the supplemental application contains reports of new clinical investigations essential to the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new claim (induction of estrus in healthy weaned sows) for which the supplemental application was approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1079 is amended by revising paragraphs (c)(2) and (c)(3) to read as follows:

§ 522.1079 Serum gonadotropin and chorionic gonadotropin.

* * * * *

(c) * * *

(2) *Indications for use.* (i) *Gilts.* For induction of fertile estrus (heat) in healthy prepubertal (noncycling) gilts.

(ii) *Sows.* For induction of estrus in healthy weaned sows experiencing delayed return to estrus.

(3) *Limitations.* For subcutaneous use only.

(i) *Gilts.* For use only in gilts over 5 1/2 months of age and weighing at least 85 kilograms (187 pounds).

(ii) *Sows.* Delayed return to estrus is most prevalent after the first litter. The effectiveness has not been established after later litters. Delayed return to estrus often occurs during periods of adverse environmental conditions, and sows mated under such conditions may farrow smaller than normal litters.

Dated: September 30, 1993.

Richard H. Teske,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 93-24589 Filed 10-6-93; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 24

[T.D. ATF-350; RE: Notice No. 740]

RIN: 1512-AA89

Materials and Processes Authorized for the Production of Wine and for the Treatment of Juice, Wine and Distilling Material; Revised Alcohol Tolerance on Labels of Wine Under 7 Percent Alcohol by Volume (90F-260T)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes an updated list of materials and processes authorized for the production of wine and for the treatment of juice, wine and distilling material. The use of these materials and processes has been found to be acceptable in accordance with good commercial practice in the production, cellar treatment, and finishing of wine. ATF is also revising its regulations to change the alcohol tolerance which is allowed on wine labels where the wine contains less than 7 percent alcohol by volume.

EFFECTIVE DATE: November 8, 1993.

FOR FURTHER INFORMATION CONTACT: Robert White or Jim Hunt, Coordinators, Wine and Beer Branch, Bureau of

Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226 (202-927-8230).

SUPPLEMENTARY INFORMATION:

Background

Since 1981, ATF has been reviewing the wine treating materials and processes which were previously prescribed in title 27, Code of Federal Regulations, part 240, subpart ZZ, and which are currently prescribed in title 27, Code of Federal Regulations, part 24, subpart L. This review was undertaken in an effort to revise the regulations in this subpart to include newly developed materials and processes in use by the wine industry and to delete materials and processes which are considered to be no longer acceptable in "good commercial practice" among wine producers, such as materials and processes no longer in use in the U.S. or elsewhere.

Notice No. 543, published in the *Federal Register* of September 24, 1984 (49 FR 37527), proposed the addition or deletion of, and, in some instances, revised usage levels for, materials and processes intended for use in the production and cellar treatment of wine. In the same issue of the *Federal Register* in which Notice No. 543 appeared, ATF published T.D. ATF-182 (49 FR 37510). This Treasury decision promulgated regulations which updated the materials and processes authorized for use in the production and treatment of wine, juice, and distilling material, established a procedure for providing agency sanction of experimentation with newly developed materials and processes, and revised the procedure for adding, altering, or deleting materials and processes employed in the treatment of wine, juice, and distilling material.

Following the issuance of Notice No. 543, ATF published in the *Federal Register* of March 7, 1986 [51 FR 8098], a notice (Notice No. 584) proposing extensive revisions to the regulations in part 240 for the production of wine. The purpose of the proposed revisions was to simplify, to modernize, and, where possible, to liberalize the wine regulations to achieve a reduced regulatory burden and a resource savings for the regulated wine industry and the Federal Government. Notice No. 584 also proposed the recodification of the regulations in part 240 into a new part 24.

On June 19, 1990, ATF published in the *Federal Register* (55 FR 24974) a Treasury decision (T.D. ATF-299) which totally revised the wine regulations and recodified part 240 into a new Part 24. As part of this overall

recodification, the Treasury decision revised the wine treating material regulations in §§ 240.1051, 240.1051a, and 240.1051b and recodified these sections into 24.246, 24.247, and 24.248. These regulation changes updated the lists of materials and processes authorized for use in the production of wine and in the treatment of wine, juice and distilling material. The preamble of the Treasury decision contained a listing of the commenters to Notice Nos. 543 and 584 and a detailed summary of the comments received with the exception of the comments on sulfites. Further action concerning the maximum permissible level of sulfites in wine was not taken due to the proposal (53 FR 51065) by the Food and Drug Administration (FDA) to lower the maximum level of sulfiting agents in wine from 350 parts per million (ppm) to 275 ppm. ATF is still awaiting final action by FDA before proceeding further in this area.

Since T.D. ATF-299 was published, there have been requests to use several new wine treating materials and processes as well as requests to change the limitations on some currently approved wine treating materials and processes. In addition, ATF has for some time been considering the delisting of several wine treating materials because we did not feel that these materials were currently being used by wine producers.

Consequently, on June 3, 1992, ATF published a notice of proposed rulemaking, Notice No. 740, in the *Federal Register* (57 FR 23357) which requested public comment on the following specific proposals:

- (1) Delisting of ammonium carbonate as a yeast nutrient for the fermentation of wine;
- (2) Delisting of the proteolytic enzymes to reduce or to remove heat labile proteins;
- (3) Reduction of the pH limitation from 3.0 to 2.5 for ion exchange;
- (4) Increasing the residual level of copper which can be contained in finished wine from 0.2 to 0.5 part per million when copper sulfate is added to wine to remove hydrogen sulfide and/or mercaptans;
- (5) Allowing the use of dimethyl dicarbonate (DMDC) in finished wine in the process of being bottled at a level not to exceed 200 parts per million; also allowing the use of DMDC in bulk wine being held for bottling between the time of the final "bottle polish" filtration and the actual filling of the bottles if the total quantity of DMDC in the wine at no time exceeds 200 ppm;
- (6) Allowing the use of polyvinylpyrrolidone (PVPP) to

remove excess color from wine and/or juice at a level not to exceed 60 pounds of PVPP per 1,000 gallons of wine or juice. All PVPP must be filtered out of the treated wine;

(7) Allowing the use of tartaric acid to reduce the pH of juice and/or wine where ameliorating material is used in the production of grape wine;

(8) Delisting of carbohydrase (*alpha*-Amylase), carbohydrase (*beta*-Amylase), and carbohydrase (Glucoamylase, Amyloglucosidase) enzymes to convert starches to fermentable carbohydrates;

(9) Delisting the use of hydrogen peroxide to remove color from the juice of red and black grapes;

(10) Allowing the use of pasteurized milk to clarify white wine;

(11) Allowing the use of low Brix juice produced by thermal gradient processing in the production of wine;

(12) Allowing the additional use of calcium carbonate (with or without calcium salts of tartaric and malic acids) to reduce excess natural acidity in high acid juice prior to or during fermentation;

(13) Allowing the additional use of potassium carbonate and/or potassium bicarbonate to reduce excess natural acidity in high acid juice prior to or during fermentation;

(14) Allowing the unrestricted use of oxygen and compressed air in juice and wine rather than restricting their use to baking or maturing wine and aeration of sherry as currently authorized in § 24.246.

In addition, ATF asked for comments concerning its proposal to revise 27 CFR 24.257(a)(4) to change the alcohol tolerance which is allowed on wine labels where the wine contains less than 7 percent alcohol by volume. The new tolerance proposed was plus or minus .75 percent by volume rather than the currently stated 10 percent of the alcohol content stated on the label.

Public Comments

ATF received 17 comments concerning its various proposals in Notice No. 740 during the 30-day comment period. A summary of the comments on each proposal is shown below, along with ATF's decision on each proposal.

Ammonium Carbonate

Three persons commented on the proposal to remove ammonium carbonate from the list of authorized wine treating materials in 27 CFR 24.246. All three commenters, including the Wine Institute, recommended removing this material from the authorized list since ammonium carbonate is not currently being used as

a yeast nutrient to facilitate fermentation of nutrient-deficient musts. Since ammonium carbonate is not currently in use by the wine industry, we are removing this material from the authorized list in 27 CFR 24.246.

Proteolytic Enzymes

ATF received seven comments in response to our proposal to delist the proteolytic enzymes. ATF proposed delisting these enzymes because we did not feel they were currently being used by the wine industry for the intended technical effect of reducing or removing heat labile proteins. All seven commenters who responded to this proposal strongly opposed delisting the proteolytic enzymes. One commenter stated that he used proteolytic enzymes during the processing of his 1991 vintage in an attempt to reduce heat labile proteins in Sauvignon blanc. According to this commenter, this variety and others often develop high protein levels. The commenter stated that it is occasionally difficult to heat stabilize these wines without using excessive amounts of bentonite, the other listed agent for this purpose. According to this commenter, the development of these enzymes by their manufacturers is ongoing, and refinements and improvements are being made which offer hope for improvements in wine processing in a natural manner.

The Wine Institute commented that while commercial proteases currently available may not have been specifically designed to remove heat labile proteins from wines, a few of the Wine Institute's members find them essential and extremely important, especially in the production of late harvest wines where heat stability by traditional means is difficult. Since proteolytic enzymes continue to be used in wine production to reduce or remove heat labile proteins, the Wine Institute requests that they not be delisted.

After reviewing the comments on the proteolytic enzymes, ATF has determined that they continue to be used by the wine industry for the technical effect of reducing or removing heat labile proteins. Consequently, these enzymes will continue to be listed as authorized wine treating materials in 27 CFR 24.246.

Ion Exchange

One commenter to Notice No. 584 suggested that the limitation for reduction of pH by ion exchange be changed from the currently prescribed pH of 3.0 to pH 2.5. The reason given for requesting this change was that

"many times it is necessary to go below pH 3 to remove potassium."

In response to this proposal, ATF received two favorable comments and one opposed to the proposal. The Wine Institute favors this proposal since juices and wine with high potassium can be stabilized with hydrogen ion exchange, and there are occasions when the pH 3.0 limitation is restrictive. Further, the Wine Institute contends that this change should be allowed for all wines and juices rather than be restricted to other than *Vitis vinifera* wines and juices only. According to this commenter, wines and juices derived from *Vitis vinifera* grapes are the ones most likely to require this kind of treatment.

The commenter who opposes this proposal states that there is no need to go to this pH value in order to remove potassium from juice or wine as claimed by the one commenter. He states that the proposed pH value of 2.5 is well below the natural pH values of wines and therefore should not be adopted.

After doing additional research on this issue, ATF has decided on a pH limitation for ion exchange of 2.8 rather than the proposed 2.5. ATF does not feel that there is a need to go below pH 2.8 to remove potassium. In addition, the pH 2.8 level seems appropriate since the natural pH values of wines do not go below this level. If, for some exceptional reason, a proprietor feels that it is imperative to go below pH 2.8, the proprietor can submit a request to ATF under 27 CFR 24.250, along with a full explanation as to why it is necessary to go below pH 2.8. ATF may approve such a request on a case by case basis if there is sufficient justification for such approval.

Copper Sulfate

Regulations in 27 CFR 24.246 prescribe a residual level limitation of 0.2 part per million of copper in wine when copper sulfate is added to wine to remove hydrogen sulfide and/or mercaptans. This limitation does not take into consideration the level of copper present in untreated wine prior to the addition of copper sulfate. Studies of the use of copper sulfate in the treatment of wine (e.g., Thoukis, George, Chemistry of Wine Stabilization: A Review, IN: Chemistry of Winemaking, A.D. Webb, Ed., American Chemical Society, Washington, DC, 1974) reveal that the treated wine is stable with residual copper levels not exceeding 0.5 part per million. An increase from 0.2 to 0.5 part per million in residual copper, if authorized, would provide winemakers added flexibility in the use of copper

sulfate and would eliminate the need to employ additional treatment to reduce the residual copper to 0.2 part per million.

ATF received five comments in favor of this proposal and none opposed. All of the commenters feel that the current residual copper limit is too low and that the proposed increase reflects good commercial practice. The commenters stated that the proposed change would eliminate the need to employ additional treatment to reduce the residual copper to 0.2 ppm and would increase winemaking flexibility in correcting odors in both still and sparkling wine.

One commenter stated that this proposal should be adopted since cupric ions are often complexed or removed from solution reactions by proteins and other species in wine. This commenter states that the removal of sulfides and thiols (mercaptans) can only be achieved if free cupric ions are present and in some wines these levels are necessary.

Another commenter states that he is in favor of this proposal for a number of reasons. Mercaptans and hydrogen sulfides are produced in wines during fermentation. The aromas and flavors caused by these compounds can vary from minor detractors in wine quality to extremely offensive. Copper sulfate additions can change a flawed wine into a very good wine.

This commenter states that one of the main contributors to sulfide compounds in wine is yeast metabolism of elemental sulfur during fermentation. The source of elemental sulfur is residual from mildew control in the vineyards. Currently, winemakers have the option of using other, non sulfur containing compounds for mildew control in the vineyard. If this option were for some reason to become unavailable, the alternative would be to use more sulfur in the vineyard, thus resulting in potentially more sulfide production during fermentation and an increased need for higher levels of copper sulfate additions to correct the defect. This commenter states that at one time he could remove the excess copper with a cyanide compound to meet the legal requirements for residual copper. However, this is no longer an option. Consequently, from a winemaking standpoint, having allowable levels of residual copper of up to 0.5 ppm is much more preferable than the alternatives which are flawed wine or moldy grapes.

After reviewing the comments, ATF agrees that there is a need to increase the residual level of copper which can be contained in finished wine from 0.2 to 0.5 parts per million (0.5 mg/L).

Consequently, ATF is revising the reference or limitation column in 27 CFR 24.246 for copper sulfate to reflect this change.

Dimethyl Dicarbonate (DMDC)

In June of 1988, ATF received an application from a winery to use dimethyl dicarbonate (DMDC) in wine. The winery application stated that DMDC has proven useful in wine as a cold beverage sterilant effective against yeast, bacteria and molds. DMDC acts by inactivating enzymes in the micro-organisms present in the wine. DMDC hydrolyzes in the wine forming principally carbon dioxide and methanol.

The application further stated that compared to other stabilization methods, such as flash pasteurization and chemical methods, DMDC is more effective in controlling problematic micro-organisms and does not lead to the development of resistant strains. Additionally, DMDC has no effect on the taste, color or odor of wine, unlike flash pasteurization or other chemical preservatives.

The winery application was submitted under former 27 CFR 240.1053 (Application for use of new treating material or process). This section of regulations has since been recodified and can now be found in 27 CFR 24.250. All required information was submitted with the application except for documentary evidence of the U.S. Food and Drug Administration's (FDA's) approval of the material for its intended purpose in the amounts proposed for the particular treatment contemplated.

In the October 21, 1988, issue of the *Federal Register*, 53 FR 41325, FDA published a final rule amending the food additive regulations by adding 21 CFR 172.133 to provide for the safe use of DMDC as a yeast inhibitor in wines. The effective date was October 21, 1988.

FDA's final rule states, in part, that DMDC (CAS Reg. No. 4525-33-1) may be safely used in wine in accordance with the following conditions:

(a) The additive meets the following specifications:

(1) The additive has a purity of not less than 99.8 percent as determined by the titration method specified in 21 CFR 172.133(a)(1).

(2) The additive contains not more than 2,000 parts per million (0.2 percent) dimethyl carbonate as determined by a method entitled "Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate," which is incorporated by reference in accordance with 5 U.S.C. 552(a).

(b) The additive is used or intended for use as an inhibitor of yeast in wine under normal circumstances of bottling where the viable yeast count has been reduced to 500 per milliliter or less by current good manufacturing practices such as flash pasteurization or filtration. The additive may be added to wine in an amount not to exceed 200 parts per million (ppm).

Upon receiving notification of FDA's approval of DMDC for use in wine, ATF approved the winery application to use DMDC in all standardized wines subject to all FDA restrictions on its use. ATF has been approving similar applications to use DMDC on a case by case basis pending final action on its use.

ATF has received an additional inquiry from the wine industry concerning the use of DMDC in bulk wine being held for bottling between the time of the final "bottle polish" filtration and the actual filling of the bottles.

ATF contacted FDA concerning this request and received the following reply. FDA has no objection to the use of DMDC to treat wines being held in tanks between the time of the final "bottle polish" filtration and the actual filling of the bottles as long as the requirements in 21 CFR 172.133 are complied with.

Furthermore, as long as the addition of DMDC to wine in a closed storage tank is the last processing step before bottling, FDA has determined that this use of DMDC constitutes "normal circumstances of bottling" as specified in § 172.133. Although the wine to be treated with DMDC in this manner must be finished and must not undergo any additional manufacturing processes, FDA has determined that the finished wine treated with DMDC may be blended with another wine as long as the 200 parts per million (ppm) overall limitation on the addition of DMDC to wine is not exceeded.

ATF received seven comments on the use of DMDC in wine and all seven comments favored its use. One commenter stated that DMDC is effective at killing any residual yeast which may have reached the bottle. The key concept is DMDC's ability to "kill" yeast rather than merely inhibiting their growth. Secondly, DMDC does not alter the organoleptic qualities of the wine since, within hours of its use it hydrolyzes into small amounts of carbon dioxide and methyl alcohol, both of which are naturally occurring substances in wine.

Another commenter states that the use of dimethyl dicarbonate provides wineries with a safe, efficient and effective means of controlling the

growth of yeast in wine. Consequently, this commenter urges its addition to the authorized wine treating material list in 27 CFR 24.246.

An additional commenter states that ATF could improve the section relating to the holding of wines prior to bottling by placing a limit on the total DMDC addition to any bottled wine of, for example, 400 mg/L. This commenter states that this limit would be twice the approved level for a single addition and repeated additions should only be necessary if the wine being held is recontaminated or held for much longer than usual times. The commenter states that unless such a limit is made, wines with significantly higher methanol contents could result from repeated applications within the regulated use.

ATF feels that the above commenter has misinterpreted the 200 parts per million (200 mg/L) limitation on the use of DMDC in wine. The 200 parts per million limitation is a cumulative total of DMDC which can be added to wine. In no case can DMDC be added again to wine if the cumulative total of DMDC which has already been added to the wine is 200 parts per million. Consequently, if wines are properly treated with DMDC in accordance with the 200 parts per million cumulative limitation, these wines should not have significantly higher methanol contents.

The final commenter on DMDC, the Wine Institute, stated that its members support the proposals concerning the use of DMDC. In addition, the Wine Institute stated that it agrees with the cumulative concentration limitation of 200 parts per million, and further supports the use of DMDC for all wines, including dealcoholized wines. Furthermore, the Wine Institute requested that ATF urge the Food and Drug Administration to approve the food additive petition filed by Mobay Corporation for the use of DMDC for all wines.

On January 26, 1993, FDA published a final rule in the *Federal Register* (58 FR 6088), effective on the same date, which amended the food additive regulations to provide for the safe use of DMDC as a yeast inhibitor in dealcoholized and low alcohol wines. FDA regulations at 21 CFR 172.133 now state that DMDC (CAS Reg. No. 4525-33-1) may be safely used in wine, dealcoholized wine, and low alcohol wine. This additional approval of the use of DMDC in dealcoholized and low alcohol wines is conditioned on its being used as an inhibitor of yeast in dealcoholized wine and in low alcohol wine under normal circumstances of bottling where the viable yeast count has been reduced to 500 per milliliter or

less by current good manufacturing practices such as flash pasteurization or filtration. The additive may be added to dealcoholized wine or low alcohol wine in an amount not to exceed 200 parts per million (ppm).

After reviewing all the comments received concerning DMDC, including the recent FDA approval of DMDC in dealcoholized and low alcohol wines, ATF has decided to approve its use in wine, dealcoholized wine, and low alcohol wine at a maximum cumulative level of 200 parts per million as long as all the requirements contained in FDA regulations at 21 CFR 172.133 are complied with. This new wine treating material is being added to the authorized list in ATF regulations at 27 CFR 24.246.

Polyvinylpolypyrrolidone (PVPP)

Several years ago, ATF received an application from a winery to use polyvinylpolypyrrolidone (PVPP) to remove excess color from "blush" type wines. The application requested that up to 60 pounds of PVPP per 1,000 gallons (7.16 g/L) of wine be authorized for use. The winery submitting the application felt that PVPP has an advantage over some currently approved color removal methods in that it has less effect on the vinous character of the wine than some of the other methods. The winery stated that PVPP is a well known material which leaves no treatment residues in the wine, as it is completely insoluble in wine. PVPP simply attracts the undesirable components of the wine to itself. The winery stated that all PVPP will be filtered out of the treated wine.

Before and after samples of "blush" wine treated with up to 60 pounds of PVPP per 1,000 gallons of wine were analyzed by the ATF laboratory. The laboratory evaluation data revealed no significant change in the wine other than the visible color change and the reduction of the spectrophotometric measurement resulting from the PVPP treatment. The analysis also indicated that all PVPP had been removed from the treated wine.

After analyzing the application, including the laboratory results of the before and after samples of the treated wine, ATF approved the winery application to use up to 60 pounds of PVPP per 1,000 gallons of wine for the purpose of removing color from red or black wine or red or black juice. Our approval was contingent on the winery following the prescribed conditions listed in Food and Drug Administration (FDA) regulations at 21 CFR 173.50 with the exception that PVPP may be used as a stabilizing agent and to remove color

from red or black wine and red or black juice rather than just as a clarifying agent.

ATF has been approving applications from other wineries to use PVPP to remove color from juice/wine on a case-by-case basis pending final action on this issue through the rulemaking process. Accordingly, ATF proposed in Notice No. 740 that PVPP be allowed for use in the production of wine to remove color from red or black wine or juice at a maximum level of 60 pounds per 1,000 gallons (7.19 g/L). PVPP had already been approved by ATF for use in wine production to clarify and to stabilize wine at a maximum level of 6.7 pounds per 1,000 gallons (0.8 g/L).

ATF received three comments to Notice No. 740 concerning PVPP. All three comments were in favor of the proposal. However, one commenter stated that the PVPP limit should be eliminated entirely since the agent is insoluble and there is no risk of a soluble residue. This commenter states that PVPP is an adsorbent and not actually a "clarifying agent." PVPP is used for the adsorptive reduction of phenol concentration. He states that the first listed use of PVPP (to clarify and to stabilize wine) is simply a subset of the second use (to remove color from red or black wine or juice) in which the coloring components (also phenols) are removed. This commenter indicates that there is no need for both descriptions.

In addition, this same commenter states that the application of dense-bed contacting technologies using this agent cannot be accomplished at even the proposed levels (60 lb/1000 gal), even though the effective proportions of agent to wine would be equivalent to less than 10 lb/1000 gal when the aggregate volume of wine is considered. The use of such levels of agent permit the lowering of phenolic components that do not have a strong affinity for PVPP. Furthermore, this commenter states that the use of dense-bed treatments would also permit the regeneration of the agent and reduce the quantity of waste materials associated with the treatment.

And finally, the Wine Institute commented that it supports the use and concentration levels proposed for PVPP. In addition, this commenter states that the use of PVPP provides greater flexibility to winemakers in the treatment of red and black juices for the control of color in the production of "blush" type wines.

ATF agrees that the use of PVPP to clarify and to stabilize wine can be considered a subset of the second stated use which is to remove color from red or black wine or juice. Consequently, ATF is combining these two uses into

one which will state that PVPP can be used to clarify and to stabilize wine and to remove color from red or black wine or juice. The reference or limitation column for PVPP in 27 CFR 24.246, as proposed in Notice No. 740, is also being changed to eliminate the paragraph listed immediately to the right of the first use of PVPP and to make the second paragraph listed immediately to the right of the second use of PVPP apply to all uses. In addition, after reviewing all the comments on PVPP, ATF has decided to retain the 60 lbs/1,000 gals. (7.19 g/L) limitation as proposed in the notice.

ATF will give further consideration to the comment concerning dense-bed contacting technologies using PVPP. If, after further review, ATF decides there is merit to this comment, we may include this comment as a proposal in a future notice of proposed rulemaking.

Use of Acid To Correct Natural Deficiencies (§ 24.182)

ATF proposed in Notice No. 740 to revise § 24.182(a) to allow the use of tartaric acid to reduce the pH of juice or wine where amelioration material is used in the production of grape wine. This would provide wineries with an alternative method to reduce pH if they do not wish to use the ion exchange method. Currently, wineries cannot add tartaric acid to their juice or wine if they are going to ameliorate their wine. This proposal would allow wineries who have ameliorated, or who are going to ameliorate, their wine to use tartaric acid to lower their pH. However, if tartaric acid is used to reduce the pH, Notice No. 740 proposed an added requirement that the fixed acid level of the juice be measured prior to the addition of any tartaric acid to determine the maximum quantity of ameliorating material allowed.

ATF requested comments on whether the use of tartaric acid to reduce the pH of grape juice/wine where ameliorating material is used is in accordance with good commercial practice. ATF also requested comments on what limit should be placed on the reduction of pH of the juice/wine if this proposal were to be adopted. ATF tentatively proposed that the pH cannot be reduced below 3.0 when adding tartaric acid to ameliorated grape juice or wine (ATF tentatively proposed a pH 2.5 limit for ion exchange which has subsequently been changed to 2.8). ATF also requested comments on whether a pH 3.0 limit would be consistent with good commercial practice and whether there should be a different limit for *Vitis vinifera* wine versus wine made from other grapes.

In response to this proposal concerning the use of tartaric acid in ameliorated wines, ATF received four comments. Two were in support of the proposal, one was in support under certain conditions, and one was opposed to the proposal.

One of these commenters stated that the use of tartaric acid should be permitted provided that the ameliorating material is grape juice or grape wine. Another commenter stated that he was opposed to the proposal. This commenter stated that wines (or juices) which have been or are going to be ameliorated should not be acidulated. He indicates that one ameliorates to correct deficiencies, e.g., insufficient sugar content. One also ameliorates to reduce excesses, e.g., excess acid (water is added to dilute the acid; then sugar is added to bring the sugar level back up). This commenter states that adding acid after adding water to dilute the acid would seem to allow the producer to stretch the total amount of wine. This would consequently give the producer an unfair economic advantage. This commenter indicates that an alternative solution would be to allow the winemaker to add tartaric acid only if no water has been added as ameliorating material.

After reviewing the comments on tartaric acid, ATF has decided to adopt the proposal to allow the reduction of the pH of grape juice/wine to not below pH 3.0 where ameliorating material is used in the production of grape wine. This change is for both *Vitis vinifera* wine and for wine made from other grapes.

ATF is adopting this proposal on tartaric acid because of the problem posed by wines having both high acidity and high pH. In such a case, the wine needs to be ameliorated to reduce the high acidity. The wine also will need to have tartaric acid added to reduce the pH, unless the winery can afford to use the ion exchange process for this purpose. The amelioration credit must be calculated prior to the pH adjustment with tartaric acid. Consequently, the amelioration credit will not be increased due to the pH adjustment. Tartaric acid is therefore being approved for use in ameliorated grape wine (or juice) for the purpose of reducing the pH down to not below pH 3.0, not for the purpose of correcting natural deficiencies in ameliorated wine/juice.

ATF also proposed in Notice No. 740 to revise § 24.182(b) to make this paragraph clearer. Several persons had questioned the meaning of § 24.182(b) in regard to the quantity of acids which can be added either prior to or during

fermentation. Some proprietors had interpreted the first sentence of § 24.182(b) to mean that any amount of acids can be added to juice/wine prior to or during fermentation. These proprietors pointed out that the limitation on the quantity of fixed acid in the finished wine is not stated until the second sentence which prescribes the types of acids which can be added to wine after fermentation is completed. The limitation prescribed is that the fixed acid level of the finished wine (calculated as tartaric acid) may not exceed 9.0 grams per liter. An exception to this limitation for high solids wine is also stated in this paragraph. Prior regulations on this subject may have been clearer because, at that time, a comma was used to divide what is now the first two sentences of § 24.182(b).

Since in prior regulations these first two sentences were just one extremely long sentence, it was easier to see that the limitation on the quantity of fixed acid in the finished wine included any acid added to correct natural deficiencies whether the acid was added prior to, during, or after fermentation.

ATF received no comments in response to this proposal to clarify § 24.182(b). Consequently, since it appears that § 24.182(b) is ambiguous as currently written, ATF is revising this paragraph to make clear that all acid added to wine to correct natural deficiencies, whether added before, during, or after fermentation, is to be included when determining whether the fixed acid level of the finished wine (calculated as tartaric acid) exceeds the prescribed limitation.

Carbohydrase Enzymes

In Notice No. 740, ATF requested comments on whether the following carbohydrase enzymes should be removed from the wine treating material list in 27 CFR 24.246: *alpha*-Amylase, *beta*-Amylase, Glucoamylase, and Amyloglucosidase. Currently, these enzymes are listed both in the wine treating material list and in 27 CFR 24.247 (Materials authorized for the treatment of distilling material). ATF asked whether these enzymes are being used by wine producers in the treatment of wine/juice for the stated purpose of converting starches to fermentable carbohydrates or whether these enzymes are only being used in the treatment of distilling material.

ATF received no comments in support of delisting these particular carbohydrase enzymes. On the other hand, ATF received three comments in favor of retaining these carbohydrase enzymes in the list of authorized wine treating materials in 27 CFR 24.246. One

commenter stated that these carbohydrase enzymes have utility in the wine industry and, therefore, should not be deleted as approved processing materials for the treatment of wine or juice.

The Wine Institute stated that these enzymes are currently being used by wine producers and have been used for years when the presence of excessive levels of starch impede normal processing of must and juice. Further, these enzymes provide winemakers with flexibility in converting residual starch materials to fermentable carbohydrates and incidentally allow increased filterability of treated juices and wines. In conclusion, the Wine Institute stated that these enzymes are necessary in wine production and should not be delisted.

After reviewing the comments concerning these carbohydrase enzymes, ATF has determined that such enzymes are still being used by the wine industry for the purpose of converting starches to fermentable carbohydrates. Consequently, ATF is retaining these enzymes as authorized wine treating materials in 27 CFR 24.246.

Hydrogen Peroxide

In T.D. ATF-299, ATF stated that hydrogen peroxide was not being removed from the list of authorized wine treating materials at that time because it was still being used by a few wineries to remove color from the juice of red and black grapes. However, we stated that ATF continues to have some reservations about the chemical changes resulting from the use of hydrogen peroxide to decolorize juice. One problem which has been brought up by several industry members is that hydrogen peroxide is a strong oxidizing agent which will add carbonyl groups, convert ketones and aldehydes to acids, break chains, interrupt resonance structures of many phenolic molecules, and give rise to quinoid structures which can quickly polymerize.

In addition, the Wine Institute, which represents hundreds of wineries, stated in a previous comment that they do not consider the use of hydrogen peroxide to remove color from the juice of red and black grapes to be in accordance with good commercial practice. Therefore, in Notice No. 740, ATF requested comments from all interested parties concerning whether the use of hydrogen peroxide to decolorize grape juice is considered to be in accordance with good commercial practice.

ATF received three comments concerning hydrogen peroxide and all three commenters favored the delisting of this material from the authorized

wine treating material list in 27 CFR 24.246. One commenter stated that hydrogen peroxide should be removed from the regulations since it has little relevance to common winemaking practice. Another commenter stated that they did not believe that the use of hydrogen peroxide to remove color from red or black grapes was in accordance with good commercial practice. The third commenter stated that they support the delisting of hydrogen peroxide for the reasons stated in Notice No. 740.

After reviewing the comments regarding the use of hydrogen peroxide to remove color from the juice of red and black grapes, ATF has decided that such use is not in accordance with good commercial practice. Consequently, hydrogen peroxide is being delisted from the wine treating material list in 27 CFR 24.246.

Pasteurized Milk

ATF has approved several applications from wineries under 27 CFR 24.249 to experiment with the use of pasteurized milk as a fining agent for white wine. We have allowed white wine to be fined with up to 2.0 liters of pasteurized milk per 1,000 liters of wine (0.2 percent V/V). Within this limitation, we have allowed the wineries to sell the treated wine or to use it in any commercial purpose. We have received several favorable responses from these wineries concerning their experimentation with pasteurized milk to fine white wine. Consequently, in Notice No. 740, ATF requested comments from all interested persons concerning whether the use of pasteurized milk to fine white wine is considered to be in accordance with good commercial practice.

ATF received five comments regarding the use of pasteurized milk as a fining agent for white wine. Four commenters were in favor of its use for this purpose whereas one commenter opposed such use.

One commenter stated that since milk is the natural product from which casein is derived, he feels that the use of pasteurized milk to fine white wine should be considered to be in accordance with good commercial practice.

Another commenter stated that since 1988 they have been using milk fining to enhance the transformation of white wine into a delicious beverage. This commenter stated that the use of milk is not an original idea. According to him, milk has been used on Chardonnay wine in the Burgundy region of France for many years. Since this Chardonnay is world renowned, this commenter

stated that his winery also decided to use milk to fine their Chardonnay. He states that milk fining can be thought of as a variation on a theme, a substitute for casein, which is a dry milk protein commonly used in California.

This commenter states that milk fining has become an important and integral winemaking tool which can impart many positive attributes. It is also easy to use as it can be added directly to wine, unlike casein, which requires a hydration step. This commenter feels that the acceptance of milk fining recognizes a traditional winemaking practice of France and is therefore in accordance with good commercial practice.

An additional commenter, the Wine Institute, stated that they support the proposal to allow the use of pasteurized milk to clarify white wines. They state that they assume that the proposal allows pasteurized whole or skim milk as a treatment material. In addition, the Wine Institute proposes that the use of milk be expanded to allow for its use with sherry and other fortified white wines. This commenter indicates that milk does an excellent job of lightening the color of sherry without the use of carbon.

The one commenter opposing the use of pasteurized milk as a fining agent in white wine stated that milk should not be approved since it has no obvious advantage over casein preparations yet would introduce minerals at significant concentrations. This commenter states that he is seriously concerned that the introduction of appreciable levels of calcium ions could lead to the development of a calcium tartrate instability in wines.

After reviewing all the comments on the use of pasteurized milk to fine white wine, ATF has decided to approve this material as a fining agent with the limitation that the amount used shall not exceed 2.0 liters of pasteurized whole or skim milk per 1,000 liters of white grape wine or sherry (0.2 percent V/V). ATF has decided to allow the use of this material as a fining agent in all white grape wines, to include sherry and other similar white grape wines, rather than restricting its use to white wine only. This expansion of the use of pasteurized milk as a fining agent will give winemakers added flexibility in producing their wines and is in accordance with several industry members' comments.

In regard to one commenter's concern about the possible development of calcium tartrate instability in wines treated with pasteurized milk, ATF believes that such instability is not a serious problem since experimentation

by several wineries over a period of seven or eight years has shown no evidence of calcium instability.

Thermal Gradient Processing Applied to Grape Juice

ATF has approved a winery application to apply thermal gradient technology, currently used for wine, to grape juice. The process involves taking a typical Brix juice and separating it into a low sugar fraction and a high sugar fraction. Both the low Brix and high Brix fractions will be used in wine production. While the high Brix fraction has a Brix level usually associated with concentrate, the winery stated that it is simply high Brix juice. The winery stated the high Brix juice would not be diluted with water for use in wine production.

The ATF Laboratory conducted tests, including organoleptic tests, on the low Brix juice and determined that a significant distinction could be made between low Brix juice produced by thermal gradient technology and low Brix juice produced by adding water to the juice. Consequently, we approved the winery application.

In Notice No. 740, ATF proposed to expand the use of thermal gradient processing in 27 CFR 24.248 to include the production of low Brix juice for use in wine production. ATF requested comments from all interested parties concerning whether the use of thermal gradient processing to produce low Brix juice is considered to be in accordance with good commercial practice when the juice is used in the production of wine.

Two comments were received that were in full support of this proposal whereas one comment was received that was somewhat opposed to the proposal. One of the commenters who was in full support of this proposal stated that the use of low Brix juice produced by thermal gradient processing in the production of wine would allow the production of a wine that is low in alcohol without having to remove alcohol or dilute the wine after fermentation.

The commenter who was somewhat opposed to this proposal stated that there needs to be a clearer definition of what is meant by "low Brix juice" before it can even be considered. This commenter stated that if it is to be compared to water additions its use should be restricted to those regions and wine styles in which water addition is permitted.

After reviewing the comments on this proposal, ATF has decided to approve the use of thermal gradient processing for the purpose of separating juice into

low Brix and high Brix juice fractions in the production of wine. The low Brix fraction is not considered a dilution but rather a separation. If water other than what was originally present is used in this process, then such water would have to be considered part of the amelioration material where amelioration is allowed. In regard to the high Brix juice fraction derived from this process, such fraction cannot be diluted with water for use in wine production.

Calcium Carbonate, Potassium Carbonate and/or Potassium Bicarbonate To Reduce Acidity in Juice

Currently, calcium carbonate (with or without calcium salts of tartaric and malic acids) and potassium carbonate and/or potassium bicarbonate are authorized by 27 CFR 24.246 to be used to reduce the excess natural acids in high acid wine. Recently, we received a request to use these wine treating materials earlier in the process by adding them, separately or in combination, to juice for the purpose of reducing the excess natural acidity in high acid juice prior to or during fermentation. Some winemakers state that the earlier in the process you reduce the acid, the better off you are.

In Notice No. 740, ATF proposed adding this additional use for these wine treating materials to 27 CFR 24.246. The reference or limitation column for these materials was left unchanged to read that the natural or fixed acids shall not be reduced below 5 parts per thousand (5 g/L).

ATF received three comments in favor of allowing the additional use of calcium carbonate, potassium carbonate and/or potassium bicarbonate to reduce excess natural acidity in high acid juice prior to or during fermentation. No comments were received which were opposed to this additional use of these materials. One commenter stated that the use of carbonates to reduce excess natural acidity prior to or during fermentation is good commercial practice.

Another commenter stated that these materials are currently in use (and have been for many years) for this application, even though apparently, illegally. This commenter states that it is the preferred method of treatment for these salts. This commenter further states that the addition of tartaric and/or malic acid is required in certain situations where the joint precipitation of the calcium salts of these acids is desired but limited by the low levels of one of them. In addition, this commenter stated that the existing and proposed limits related to fixed acids

are too low in his experience and could easily be raised to 6.0 or 7.0 g/L while still being within the levels ever expected in good commercial practice.

After reviewing the comments received concerning these wine treating materials, ATF has decided to approve their use in high acid juice as proposed in Notice No. 740. The reference or limitation column in 27 CFR 24.246 will continue to read that the natural or fixed acids shall not be reduced below 5 parts per thousand (5 g/L).

Oxygen and Compressed Air

Currently, the wine treating material regulations at § 24.246 authorize the use of oxygen and compressed air in the baking or maturing of wine and the aeration of sherry. The "Reference or limitation" column of this regulation states that oxygen and compressed air may be used provided it does not cause changes in the wine other than those occurring during the usual storage in wooden cooperage over a period of time. We have recently been asked by a winemaker to allow the use of oxygen and compressed air in juice in order to oxidize the pigments in the juice so the pigments can be more easily removed in order to produce "blush" type wines. This request has led us to reevaluate the purpose for the restrictions on the use of oxygen and compressed air in § 24.246.

As a result of this reevaluation process, ATF proposed in Notice No. 740 to remove the restrictions on oxygen and compressed air and to simply state that these materials may be used in juice and wine.

ATF received three comments in support of this proposal and one comment which mentions the proposal but does not express support or opposition to the proposal. One commenter states that they see no reason for the current restrictions on the use of oxygen or compressed air in winemaking. Another commenter states that the present restriction on oxygen and compressed air should be eliminated since there is commonly a need to re-aerate juices prior to yeast inoculation for normal cell viability and fermentation performance. This commenter states that this is especially so in juices that have not had sulphur dioxide added or those with ascorbic acid added.

Another commenter states that in the production of authentic sherry the use of oxygen and compressed air is not needed. This commenter further states that the use of oxygen and compressed air and other similar procedures are only used to produce imitations of the original sherry.

After viewing the above comments, ATF has decided to approve the removal of the restrictions on the use of oxygen and compressed air and to simply state that oxygen and compressed air may be used in juice and wine.

Revised Alcohol Tolerance on Labels of Wines Under 7 Percent Alcohol by Volume

The Federal Alcohol Administration Act (FAA) regulations contain labeling requirements for wines with an alcohol content of 7 percent by volume and above. The requirements for labeling wines under 7 percent alcohol by volume are in the Internal Revenue Code (IRC) wine regulations. During the revision of the IRC wine regulations, ATF determined that there was no specific provision for an alcohol tolerance on labels for wines under 7 percent by volume. The tolerances in alcohol content provided for in former 27 CFR 240.579 were those allowed under 27 CFR part 4, and, therefore, were not applicable to wine having less than 7 percent alcohol by volume.

A notice of proposed rulemaking (Notice No. 584) for the revision and recodification of the IRC wine regulations was published in the Federal Register on March 7, 1986. In that notice, ATF proposed an alcohol label tolerance for wines under 7 percent alcohol by volume of plus or minus 10 percent of the alcohol content stated on the label. At the time, wines under 7 percent alcohol by volume were wine cooler products with an alcohol content of 5 to 7 percent, which would have allowed for an alcohol tolerance of .5 to .7 percent by volume. One comment was submitted on this proposal stating that it might be preferable to have an alcohol tolerance of 1 percent, but the comment seemed to be more of an opinion rather than an objection to the wine label alcohol tolerance proposed.

On June 19, 1990, ATF published T.D. ATF-299 in the Federal Register adopting the proposal in Notice No. 584 to allow a tolerance of plus or minus 10 percent of the alcohol content stated on the label for wines under 7 percent alcohol by volume. Soon after the final rule was published, ATF was advised that the alcohol tolerance for wines under 7 percent alcohol by volume was too low and it would be very difficult to meet this tolerance for wine cooler products at 5 percent alcohol by volume and nearly impossible for the new light wine cooler products with an alcohol content of 2 to 3 percent by volume. A petition was submitted to allow a label

tolerance for alcohol content of 1 percent by volume.

After carefully considering the evidence submitted by the petitioner and other information concerning an alcohol tolerance for wines under 7 percent, ATF agrees that the alcohol tolerance of 27 CFR 24.257(a)(4) allowing a plus or minus 10 percent of the alcohol content stated on the label for wines under 7 percent alcohol by volume should be increased. However, since wines 7 to 14 percent alcohol by volume in the FAA Act regulations are allowed an alcohol tolerance of 1.5 percent by volume from that stated on the label, ATF decided that an alcohol tolerance of 1 percent for wines under 7 percent alcohol by volume might be considered too high.

Therefore, ATF proposed in Notice No. 740 a label alcohol tolerance of .75 percent for wines under 7 percent alcohol by volume. ATF received two comments in favor of the proposal and one comment suggesting an alternative to the proposal. One of the two commenters favoring the proposal states that the proposed tolerance of plus or minus .75 percent by volume, rather than the currently stated 10 percent of the alcohol content stated on the label, is welcomed. This commenter further states that it is very difficult to produce, on a commercial scale, wines of very low alcohol content within the confines of the current rule.

The commenter who suggested an alternative to the proposal states that she believes ATF should establish two new categories, each with a separate tolerance level. For wines with an alcohol content of less than 4 percent by volume, this commenter suggested an alcohol tolerance of .75, and for wines with an alcohol content less than 7 percent and greater than 4 percent, she suggested an alcohol tolerance of .5. This commenter stated that this two tier tolerance level based on alcohol content should be within the technological capabilities of wine producers and would substantially lessen the variation in alcohol content among products developed and promoted based on their lower alcohol content.

After reviewing the comments, ATF has decided to adopt the plus or minus .75 percent by volume alcohol tolerance level which was proposed in Notice No. 740. ATF believes that this tolerance level is within the capabilities of all wine producers and that consumers will be sufficiently protected against high variations in alcohol content of low alcohol products.

Harmonization of Regulations

ATF received a comment to Notice No. 740 from the National Association of Beverage Importers (NABI) concerning the harmonization of regulations between the U.S. and the European Community (EC). This commenter stated that they welcome the modernization of the regulation governing the materials and processes authorized for the production of wine and for the treatment of juice, wine and distilling materials. However, because NABI members are importers and exporters of alcohol beverages all over the world, NABI supports efforts of harmonization of the regulations that govern alcohol products. NABI therefore strongly requests that ATF attempt to harmonize their proposed regulations with those of the U.S.'s major trading partners (the European Community), before the regulations are finalized. This commenter states that harmonized regulations between trading partners enhance the two-way trade of the products in question.

In response to the NABI comment, ATF does not feel that there is any reason to believe that the changes being made by this Treasury decision will have a negative impact on harmonization efforts.

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation is liberalizing in nature and will allow large and small winemakers more flexibility when producing their wines. Accordingly, a regulatory flexibility analysis is not required because the final rule is not expected (1) to have significant secondary, or incidental effects on a substantial number of small entities; or (2) to impose, or otherwise cause a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Executive Order 12291

It has been determined that this document is not a major regulation as defined in E.O. 12291 and a regulatory impact analysis is not required because it will not have an annual effect on the economy of \$100 million or more; it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United

States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Public Law 96-511, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because no requirement to collect information is imposed.

Drafting Information

The principal author of this document is Robert L. White, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms. ATF Wine Technical Advisor Richard M. Gahagan and ATF Chemist Randolph H. Dyer have provided significant technical assistance in the evaluation and review of data pertinent to the preparation of this document.

List of Subjects in 27 CFR Part 24

Administrative practice and procedure, Authority delegations, Claims, Electronic funds transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Transportation, Warehouses, Wine and vinegar.

Authority and Issuance

27 CFR Part 24—Wine is amended as follows:

PART 24—WINE

Paragraph 1. The authority citation for part 24 continues to read as follows:

Authority: 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5081, 5111-5113, 5121, 5122, 5142, 5143, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356-5357, 5361, 5362, 5364-5373, 5381-5388, 5391, 5392, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7011, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

Par. 2. Section 24.182 is amended to revise paragraphs (a) and (b) to read as follows:

§ 24.182 Use of acid to correct natural deficiencies.

(a) *General.* Acids of the kinds occurring in grapes or other fruit (including berries) may be added within the limitations of § 24.246 to juice or wine in order to correct natural deficiencies; however, no acid may be added to juice or wine which is ameliorated to correct natural deficiencies except that in the production of grape wine, tartaric acid may be used to reduce the pH of the

juice or wine. If tartaric acid is used to correct the pH of grape juice or wine, the fixed acid level of the juice shall be measured prior to the addition of any tartaric acid to determine the maximum quantity of ameliorating material allowed. In addition, when using tartaric acid to reduce the pH of ameliorated grape juice or wine, the pH cannot be reduced below 3.0.

(b) *Grape wine.* Tartaric acid or malic acid, or a combination of tartaric acid and malic acid, may be added prior to or during fermentation, to grapes or juice from grapes. In addition, after fermentation is completed, citric acid,

fumaric acid, malic acid, lactic acid or tartaric acid, or a combination of two or more of these acids, may be added to correct natural deficiencies. However, the use of these acids, either prior to, during or after fermentation, may not increase the fixed acid level of the finished wine (calculated as tartaric acid) above 9.0 grams per liter. In cases where the wine contains 8.0 or more grams of total solids per 100 milliliters of wine, acids may be added to the extent that the finished wine does not contain more than 11.0 grams per liter of fixed acid (calculated as tartaric acid).

* * * * *

Par. 3. Section 24.246 is amended in the table by removing the entry for ammonium carbonate, and hydrogen peroxide; by revising the entry for calcium carbonate, copper sulfate, oxygen and compressed air, polyvinylpyrrolidone (PVPP), potassium carbonate and/or potassium bicarbonate and tartaric acid; and by adding the entry for dimethyl dicarbonate and milk (pasteurized whole or skim) to read as follows:

§ 24.246 Materials authorized for treatment of wine and juice.

* * * * *

Materials	Use	Reference or limitation
Calcium carbonate (with or without calcium salts of tartaric and malic acids).	To reduce the excess natural acids in high acid wine, and in juice prior to or during fermentation. A fining agent for cold stabilization	The natural or fixed acids shall not be reduced below 5 g/L. 21 CFR 184.1069 and 184.1099, and 184.1191 (GRAS). The amount used shall not exceed 30 lbs/1000 gals. (3.59 g/L) of wine.
Copper sulfate	To remove hydrogen sulfide and/or mercaptans from wine.	The quantity of copper sulfate added (calculated as copper) shall not exceed 0.5 part copper per million parts of wine (0.5 mg/L) with the residual level of copper not to be in excess of 0.5 part per million (0.5 mg/L). 21 CFR 184.1261 (GRAS).
Dimethyl dicarbonate	To sterilize and to stabilize wine, dealcoholized wine, and low alcohol wine.	Must meet the conditions prescribed by FDA in 21 CFR 172.133. DMDC may be added to wine, dealcoholized wine, and low alcohol wine in a cumulative amount not to exceed 200 parts per million (ppm).
Milk (pasteurized whole or skim)	Fining agent for white grape wine or sherry ..	The amount used shall not exceed 2.0 liters of pasteurized milk per 1,000 liters of white grape wine or sherry (0.2 percent V/V).
Oxygen and compressed air	May be used in juice and wine	None.
Polyvinylpyrrolidone (PVPP)	To clarify and to stabilize wine and to remove color from red or black wine or juice.	The amount used to treat the wine, including the juice from which the wine was produced, shall not exceed 60 lbs/1,000 gals. (7.19 g/L) and shall be removed during filtration. PVPP may be used in a continuous or batch process. The finished wine shall retain vinous character and shall have color of not less than 0.6 Lovibond in a one-half inch cell or not more than 95 percent transmittance per **AOAC Method 11.003-11.004 (14th Ed.). 21 CFR 173.50.
Potassium carbonate and/or potassium bicarbonate.	To reduce excess natural acidity in wine, and in juice prior to or during fermentation.	The natural or fixed acids shall not be reduced below 5 parts per thousand (5 g/L). 21 CFR 184.1619 and 184.1613 (GRAS).
Tartaric acid	To correct natural acid deficiencies in grape juice/wine and to reduce the pH of grape juice/wine where ameliorating material is used in the production of grape wine.	Use as prescribed in 27 CFR 24.182 and 24.192. 21 CFR 184.1099 (GRAS).

Par. 4. Section 24.248 is amended in the table by revising item 6 under the "reference or limitation" heading for ion exchange and by revising the entry for thermal gradient processing to read as follows:

§ 24.248 Processes authorized for the treatment of wine, juice, and distilling material.

Processes	Use	Reference or limitation
Ion exchange		6. Treatment does not reduce the pH of the juice or wine to less than pH 2.8 nor increase the pH to more than pH 4.5.
Thermal gradient processing	To separate wine into low alcohol and high alcohol wine fractions.	The fractions derived from such processing shall retain vinous character. Such treatment shall not increase the alcohol content of the high alcohol fraction to more than 24 percent by volume. The addition of water other than that originally present in the wine prior to processing will render standard wine "other than standard."
	To separate juice into low Brix and high Brix juice fractions.	The low Brix fraction derived from such processing may be used in wine production. The high Brix fraction derived from such processing shall not be diluted with water for use in wine production.

Par. 5. Section 24.257(a)(4) is revised to read as follows:

§ 24.257 Labeling wine containers.

(a) * * *

(4) The alcohol content as percent by volume or the alcohol content stated in accordance with 27 CFR part 4. For wine with less than 7 percent alcohol by volume stated on the label there is allowed an alcohol content tolerance of plus or minus .75 percent by volume; and

Signed: August 23, 1993.
Stephen E. Higgins,

Director.

Approved: September 20, 1993.
Ronald K. Noble,
Assistant Secretary (Enforcement).
[FR Doc. 93-24586 Filed 10-6-93; 8:45 am]
BILLING CODE 4810-10-31-U

SUMMARY: OSM is announcing approval with an exception and a required amendment of a proposed amendment to the Wyoming permanent regulatory program (hereinafter, the "Wyoming program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment, submitted July 8, 1992, pertains to wildlife monitoring. The proposed amendment revises the Wyoming program to be consistent with the corresponding Federal standards and to incorporate the additional flexibility afforded by the revised Federal rules.

EFFECTIVE DATE: October 7, 1993.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261-5776.

SUPPLEMENTARY INFORMATION:**I. Background on the Wyoming Program**

On November 26, 1980, the Secretary of the Interior conditionally approved the Wyoming program. General background information on the Wyoming program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Wyoming program can be found in the November 26, 1980, **Federal Register** (45 FR 78637). Subsequent actions concerning Wyoming's program and program amendments can be found at 30 CFR 950.11, 950.12, 950.15 and 950.16.

II. Submission of Amendment

On July 8, 1992, Wyoming submitted a proposed amendment to its program

pursuant to SMCRA (Administrative Record No. WY-18-1). Wyoming proposes to amend the following Department of Environmental Quality—Land Quality Division (DEQ/LQD) rules and regulations relating to coal exploration and coal mining and reclamation operations at chapter II, section 3(b)(iv)(B), chapter IV, section 3(o)(iv), and appendix B.

OSM published a notice, in the September 11, 1992, **Federal Register** (57 FR 41714), announcing receipt of the proposed amendment and in the same notice, opened the public comment period and provided opportunity for a public hearing on its substantive adequacy. The public comment period closed on October 13, 1992. A public hearing was not held because no one requested to testify.

During its review of the amendment, OSM identified four issues included under the following topics: 640 acre limitation, adjacent area monitoring, reporting requirements, and monitoring time-frames. OSM notified Wyoming of these issues by letter dated November 9, 1992, (Administrative Record No. WY-18-9). Wyoming responded in a letter dated January 11, 1993, to all of the issues raised by OSM (Administrative Record No. WY-18-11).

In a March 22, 1993, **Federal Register** (58 FR 15319), OSM announced receipt of the additional information from Wyoming and reopened the public comment period for the proposed amendment (Administrative Record No. WY-18-12). The public comment period closed on April 16, 1993.

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 950****Wyoming Permanent Regulatory Program**

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the OSM Director's findings concerning the amendment submitted by Wyoming on July 8, 1992, and subsequently clarified on January 11, 1993.

1. LQD Rules, Chapter II, Section 3(b)(iv)(B) and Chapter IV, Section 3(o)(iv): Monitoring Methods

Wyoming proposes to amend LQD Rules at chapter II, section 3(b)(iv)(B) to require permit information on how the applicant will utilize monitoring methods as specified in Appendix B to protect and enhance: (1) Threatened and endangered species of plants and animals listed by the Secretary under the Endangered Species Act of 1973 and their critical habitats, (2) species identified through the consultation process, and (3) important habitats. Also at chapter IV, section 3(o)(iv), Wyoming proposes to require the operator to perform periodic wildlife surveys, in the level and detail and for those areas as determined by the administrator, in accordance with appendix B.

The counterpart Federal regulations at 30 CFR 780.16(b)(3)(i) and 784.21(b)(3)(i) require the applicant to provide protective measures for fish and wildlife resources. In the preamble to 30 CFR 780.16(b)(3)(i) in the December 11, 1987, *Federal Register* (52 FR 47356), OSM emphasized that the protective measures provided as examples under this section are not an exclusive list to be considered by the applicant. The regulatory authority may also require the applicant to undertake other protective measures such as biological monitoring.

Wyoming's proposed rules make explicit that wildlife monitoring is required in accordance with appendix B for the protection of wildlife resources. Therefore the Director finds that Wyoming's proposed rules at chapter II, section 3(b)(iv)(B) and chapter IV, section 3(o)(iv), are consistent with and no less effective than the Federal regulations at 30 CFR 780.16(b)(3)(i) and 784.21(b)(3)(i) and is approving them.

2. LOD Rules Appendix B: Wildlife Monitoring Requirements for Surface Coal Mining Operations

In its appendix B, Wyoming proposes to set procedures for wildlife monitoring on surface coal mining operations. The appendix includes monitoring requirements and methodologies under five separate sections: A. Big Game Seasonal Habitat, B. Upland Game Bird Brood Counts and Lek Attendance

Surveys, C. Raptor Production, D. Migratory Birds of High Federal Interest, and E. Federally Listed Threatened and Endangered Species.

During its review of appendix B, OSM identified the following concerns:

a. Introduction: 640-Acre Limitation and Adjacent Areas

In the introduction to appendix B (first paragraph, last two sentences) Wyoming originally proposed to allow an exception to its wildlife monitoring measures so that the monitoring procedures specified in the appendix would only be applicable to surface coal mines disturbing 640 acres or more of land. Wyoming also proposed that, where landowner constraints prevent access to adjoining lands, monitoring would not be required unless it could be reasonably conducted from a distance.

The Federal rules at 30 CFR 780.16(a) and 784.21(a) and Wyoming's rules at chapter II, section 3(a)(vi)(E) (underground rules at chapter VII reference surface rules) require that fish and wildlife resource information be collected for the permit area and adjacent areas. Additionally, the Federal rules at 30 CFR 780.16(b)(2) and 784.21(b)(2) and Wyoming's rules at chapter IV, section 3(o) (underground rules at chapter VII reference surface rules) specifically require that a protection and enhancement plan be provided that addresses those wildlife resources identified.

Further, the Federal rules at 30 CFR 780.16(b)(3)(i) and 784.21(b)(3)(i) require that protective measures must be used during the active mining phase. The Wyoming rules at chapter II, section 3(b)(iv)(B) and proposed appendix B are counterparts to these Federal regulation requirements. Wyoming's rules, in addition to the federally mandated requirements, require monitoring to insure protection and enhancement of fish and wildlife resources.

As discussed in the preamble to 30 CFR 780.16(b)(3)(i) (52 FR 47356), OSM emphasized that the protective measures provided as an example under this section are not intended to be an exclusive list of the protective measures to be considered by the applicant. Other protective measures such as biological monitoring may also be considered. Therefore, Wyoming's proposal to make wildlife monitoring mandatory is consistent with Federal program requirements.

However, as originally proposed, Wyoming's monitoring requirements would preclude the requirements for wildlife monitoring on mines that disturb less than 640 acres. The proposed rules would in effect have the

potential to exempt some mines from the need to provide protective measures such as biological monitoring (wildlife monitoring). Additionally, Wyoming would provide that no monitoring is required where landowner constraints prevent access to adjoining lands unless the monitoring could be reasonably conducted from a distance. Both the Federal and State rules require that the enhancement plan and protective measures consider and include the permit area and adjacent areas. When adjacent areas are surveyed and are decided to be a critical part of the enhancement plan, they cannot be excluded.

In its January 11, 1993, letter, Wyoming proposed to revise this portion of its appendix to require that operators disturbing less than 640 acres of land may request a reduced level of monitoring through submittal of an alternative wildlife monitoring plan to be reviewed and approved by the regulatory authority prior to implementation. Additionally, the State deleted the language that would waive monitoring if landowner constraints prevent access.

With these changes, the Director finds that this portion of Wyoming's proposed appendix B will afford assurance that protective measures during mining operations will take place in a manner that is no less effective than the Federal regulation requirements at 30 CFR 816.97(b) and 817.97(b), and is approving it.

b. Section C: Raptor Production—Nest Status and Production Success—Wildlife Monitoring Time-frames

During the public comment period, the USFWS recommended the initiation of raptor surveys in mid-February to help prevent conflict situations from arising (Administrative Record No. WY-18-6). Additional clarification was obtained from USFWS on October 10, 1992 (Administrative record No. WY-18-13). The USFWS was concerned that, under appendix B, wildlife surveys would not be undertaken soon enough in the year to mitigate the adverse impacts of a mining operation on nesting golden eagles. USFWS asserted that, although golden eagles initiate nesting activities in February, the surveys proposed under appendix B would not occur until March. Under the proposal, if eagles are nesting when the survey is conducted, mitigation of the impacts from the mining operation on the nesting activity would be limited to avoiding the nesting site with a designated buffer zone. If nesting occurs in a highwall adjacent to an active mining operation and eggs have been

laid, mining activities might be required to cease until the nest is inactive. However, if an operator discovers the eagles when they are establishing the nest, the USFWS can attempt to relocate the nest or harass the birds away from the area. Therefore, the sooner the operator is aware of the nesting activity, the better the chances are of avoiding potential conflicts.

OSM notified Wyoming of the USFWS concerns and, as a result, in the January 11, 1993, letter, Wyoming modified the proposed language at section C., Raptor Production, to require that surveys of golden eagles and great horned owls be conducted in mid-February to mid-March and all other raptors from March to mid-May. This modification resolves the USFWS concern.

The Director finds that Wyoming's proposed appendix B with the exception noted at Finding 2.c. is no less effective than the Federal program requirements and is approving it.

c. Section E: Reporting Requirements

Under section E, Wyoming proposed that all observations of threatened and endangered species, except migrating and wintering bald eagles or migrating peregrine falcons, must be reported promptly to the USFWS office in Cheyenne, Wyoming. The Federal rule requirements at 30 CFR 816.97(b) and 817.97(b) require the operator to promptly report to the regulatory authority any State or federally-listed endangered or threatened species within the permit area of which the operator becomes aware. Upon notification, the regulatory authority shall consult with appropriate State and Federal fish and wildlife agencies and, after consultation, shall identify whether, and under what conditions, the operator may proceed.

Wyoming's Rule at chapter IV, section 3(o)(i)(E) (underground rules at chapter VII reference surface rules) also requires prompt reporting to the regulatory authority of any species or critical habitat or such species listed as threatened or endangered, or any golden or bald eagle nest in or adjacent to the permit area, which was not reported or investigated in the permit application.

As initially proposed, the reporting requirements of section E would (1) exclude reporting of migrating and wintering bald eagles or migrating peregrine falcons and (2) improperly direct reporting to the USFWS rather than the State regulatory authority. In its January 11, 1993, letter, Wyoming proposed to revise its reporting requirement to direct reporting to the regulatory authority rather than the USFWS. Wyoming, however did not

propose to remove the language "except migrating and wintering bald eagles or migrating peregrine falcons."

The Director finds that Wyoming's proposed appendix B, to the extent that it would not require the reporting of migrating and wintering bald eagles or migrating peregrine falcons, is less effective than the Federal program requirements and is not approving this exclusion. Wyoming is required to amend its program to remove the language "except migrating and wintering bald eagles or migrating peregrine falcons" from this portion of appendix B.

IV. Summary and Disposition of Comments

Public Comments

The Director solicited public comment on the proposed amendment and provided opportunity for a public hearing. No comments were received, and the scheduled public hearing was not held because no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Wyoming program. A summary of the comments, and the Director's responses to them, appear below:

1. The U.S. Department of Interior (USDI)—Bureau of Indian Affairs, U.S. Army Corps of Engineers, U.S. Department of Agriculture—Forest Service—Rocky Mountain Region, USDI—Geological Survey, USDI—Bureau of Mines, and USDI—Bureau of Reclamation, responded with no comment (Administrative Record Nos. WY-18-5a, WY-18-4d, WY-18-4e, WY-18-4b, WY-18-4a, and WY-18-4f).

2. The U.S. Department of Labor—Mine Safety and Health Administration (MSHA)—Washington, DC Office responded that their review found that none of the proposed modifications conflict with the regulations or policies of the MSHA (Administrative Record No. WY-18-4c).

3. The U.S. Department of Labor—Mine Safety and Health Administration—Coal Mine Safety and Health District 9 commented that these proposed changes did not appear to be in conflict with any current MSHA regulations that pertain to refuse piles and impoundments (Administrative Record No. WY-18-5b).

4. U.S. Department of Interior, Bureau of Land Management (BLM) commented that it had no suggested changes to the

proposed regulations. However, the BLM did suggest that OSM compare and cross reference the proposed rule changes with the minimum coal data adequacy standards that were developed for the regional coal teams/areas to assure consistency between these documents (Administrative Record No. WY-18-7). OSM does not agree that potential inconsistency could result since the minimum coal data adequacy standards apply only to the Federal Coal Leasing process prior to initiation of a mine operation. The standard proposed by Wyoming would be initiated at the time the operation begins. Findings of the coal data adequacy standards along with additional baseline and resource information data required of an operator in the application will assure consistency and updating of those previous findings.

5. The U.S. Department of Interior—U.S. Fish and Wildlife Service (USFWS or the Service) provided substantial comments on October 8, 1992 (Administrative Record No. WY-18-6). The comments made are summarized and discussed in the following subsections:

a. The USFWS asserts that OSM, not the State, has lead responsibility for consulting with the Service under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (ESA). See page 82, LQD Rules chapter IV, section 3(o)(i)(E). Therefore, the USFWS recommends that the section cited above be revised to denote that the State program Administrator will consult with the Service under the ESA through OSM, and that the Service and OSM shall identify whether and under what conditions the operator may proceed. USFWS pointed out that this same deficiency occurs on page 83, LQD Rules chapter IV, section 3(o)(iii), and in appendix B, page 251, section E., "Federally Listed Threatened and Endangered Species."

To clarify who is responsible for consultation with the service, OSM notes the following: Section 7(a)(2) of the ESA states that "each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species * * *". Consultation on permitting actions is conducted by the Wyoming Department of Environmental Quality, OSM, or the appropriate Federal land management agency with the USFWS in Cheyenne, Wyoming. Several different factors

determine which agency will be responsible for the consultation with the USFWS, as discussed below:

Permitting Actions Involving Leased Federal Coal

Under the Cooperative Agreement with Wyoming at Federal regulations 30 CFR 950.20, for operations involving leased Federal coal, OSM retains responsibility for compliance with the ESA. When species listed as threatened or endangered or their critical habitat are encountered during a mining operation, the approved Wyoming regulations at LQD Rules, chapter IV, section 3(i)(E), and chapter IV, section 3(iii), require the operator to contact the Regulatory Authority (RA). The RA must then consult with the Wyoming Game and Fish Department (WGFD) and the USFWS to determine under what conditions the operation may proceed. These approved regulations correspond with the Federal regulations at 30 CFR 816.97(b). The preamble to the approval of 30 CFR 816.97 states that section 816.97 "[i]s intended to satisfy OSM's responsibility under the ESA and to provide protection for endangered or threatened species * * * (48 FR 30317).

After being contacted by the RA, if the USFWS determines that the operation may affect a listed species or critical habitat that has not been previously consulted on, the USFWS would re-initiate consultation with OSM under Section 7 of the ESA. This process is described in the Interagency Cooperation Regulations found at 50 CFR 402. If the USFWS did not re-initiate Section 7 consultation and a mine plan modification was necessary to mitigate the impacts to the species, OSM would then make a decision on re-initiation of Section 7 consultation after reviewing the revision. OSM routinely reviews Federal permits for compliance with the ESA whenever a mining plan modification is reviewed.

Permitting Actions on Non-Federal Lands

The Memorandum of Understanding (MOU) between OSM and the USFWS of February 7, 1983, establishes the procedures for coordination between the two agencies under the provisions of SMCRA and the ESA. The MOU, at page 4, specifically states that the approval of a State program does not "federalize" the State permitting process and, therefore, the State does not have responsibility to conduct section 7 consultation under the ESA. However, OSM's approval of the State program does require formal consultation with the USFWS to determine if the program

will affect threatened or endangered species. The MOU specifically states, at page 5 that, "[p]rior to permit approval, the regulatory authority must find in writing, * * * [t]hat the mining operation would not affect the continued existence of threatened or endangered species or result in the destruction of their critical habitats."

The Federal regulations at 30 CFR 773.15(c) (10) require the regulatory authority to make a finding that the operation in question would not affect the continued existence of endangered or threatened species or result in a destruction or adverse modification of their critical habitats for Federally listed species for all permit applications and significant revisions. Wyoming's LQD Rules at chapter IV, section 3(o)(iii), require a finding that the surface mining operation in question is not likely to jeopardize the continued existence of endangered or threatened species listed by the State or the Secretary, in violation of the Endangered Species Act. The Wyoming regulations require denial of an application if the application is not complete. In the approval of the State program, the Secretary determined that Wyoming's permit application review provisions were as stringent as the Federal regulations because Wyoming was judging the complete application against all applicable regulations including the plan for protecting threatened or endangered species (45 FR 78668).

As discussed in Finding 2.c., Wyoming's program requires an operator to contact the RA when threatened or endangered species are encountered on the permit area. The RA then contacts the WGFD and the USFWS to determine under what conditions the operation may continue. OSM has the lead role in continuing to monitor the State's program to ensure that no threatened or endangered species or its critical habitat is jeopardized. OSM's oversight of the State program ensures that the operator's and the State's actions comply with the ESA.

Permitting Actions on Federal Lands

Under the Cooperative Agreement with Wyoming, OSM's primary role is one of coordination between the RA and the Federal agency with jurisdiction or responsibility over the Federal lands affected by the proposed operation. The Federal land management agency responsible for the surface rights (Bureau of Land Management, U.S. Forest Service, etc.) is responsible for the Section 7 consultation on their lands affected by the proposed operation.

Wyoming is responsible for issuing surface mining permits for surface mining operations conducted on Federal lands within its borders. OSM has the responsibility for forwarding permit revisions and renewal information to the Federal land management agency, but no adequacy determinations are made by OSM.

b. The USFWS expressed concern that the wildlife monitoring requirements be utilized for all surface coal mines, not just mines that disturb 640 acres or more of land. See Appendix B, page 245, paragraph 1. OSM agrees, as discussed at Finding 2.a., and has required Wyoming to include monitoring requirements for mines that disturb 640 acres or less.

c. The USFWS recommended that, in cases where landowner constraints prevent access to adjoining lands, as much information as possible should be obtained by aerial surveys. The USFWS also recommended that the State Program Administrator closely monitor operators who take advantage of this provision to ensure that the operator does not use it as a excuse to reduce the extent of wildlife monitoring. See appendix B, page 245, paragraph 1. OSM agrees with USFWS recommendation, as discussed in Finding 2.a., and has requested the State to require monitoring of all adjoining lands.

d. The USFWS recommended that, to prevent a conflict situation from arising, raptor nest surveys for golden and bald eagles and great horned owls should be initiated in mid-February and continue through March. For other raptors, the USFWS recommended that nest surveys be initiated in mid-March and continue through May. The USFWS also recommended that these dates and the raptor species to be inventoried be further refined in the raptor mitigation plan developed for each mine. See Appendix B, Section C, Raptor Production. OSM agrees with the USFWS recommendations, as discussed in Finding 2.b., and has requested the State to require a wider span of dates for surveys.

e. The USFWS commented on appendix B, Permit Term Mitigation Plan and the Migratory Birds of High Federal Interest Plan, that refer to coordination between the operator and the USFWS. The proposed wildlife monitoring guidelines require that both plans be approved by the USFWS prior to permit approval. OSM agrees with the recommendations by the USFWS that these plans should be handled on a case-by-case basis during their review and approval of the plans as clearly defined in appendix B at the above

referenced sections. OSM assumes that this is the current process and that it will continue.

f. The USFWS noted that the Service's Wyoming State Office in Cheyenne should be contacted to verify procedures to use to conduct black-footed ferret searches instead of the Service's Regional Endangered Species Office. OSM advises Wyoming to contact the USFWS to coordinate this matter.

State Historic Preservation Office (SHPO) and Advisory Council on Historic Preservation (ACHP) Comments

As required by 30 CFR 732.17(h)(4), OSM provided the proposed amendment to the SHPO and ACHP for comment. No comments were received from the ACHP or the Wyoming Division of Parks and Cultural Resources—State Historic Preservation Office.

Environmental Protection Agency Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

On October 1, 1992, the EPA concurred with Wyoming's proposed amendment. The EPA stated, "EPA concurs with the proposed amendment as we find that it demonstrates the legal authority, administrative capability, and the technical conformity with controlling National Pollutant Discharge Elimination System regulations necessary to maintain water quality standards promulgated under the authority of the Clean Water Act (CWA), as amended (33 U.S.C. 1251 *et seq.*). We wish to note, however, that with regard to Chapter IV, section (ii), stream buffer zone, EPA's interpretation of waters of the United States at 40 CFR 122.2 includes perennial, intermittent, and ephemeral streams. All discharges of pollutants (including waste and fill material) to these waters must be in compliance with sections 402 and 404 of the CWA" (Administrative Record No. WY-18-8). EPA's comments regarding LQD Rules, chapter IV, section 3(o)(ii), are noted. However, Wyoming has not proposed to modify those rules in this amendment and therefore, those rules are not subject to review.

V. Director's Decision

Based on the above findings, the Director approves Wyoming's proposed program amendment as submitted July 8, 1992, and January 11, 1993, with the exception of the provision set forth at Finding 2.c. concerning the reporting of migrating and wintering bald eagles or migrating peregrine falcons. The Director is requiring a program amendment at 30 CFR 950.16 as discussed in Finding 2.c.

The Federal regulations at 30 CFR part 950 codifying decisions concerning the Wyoming program are being amended to implement this decision. The Director is approving these regulations with the provision that they will be fully promulgated in a form identical to that submitted to and reviewed by OSM. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undo delay. Consistency of State and Federal standards is required by SMCRA.

VI. Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary of the Interior. Federal regulations at 30 CFR 732.17(a) require that any alteration of an approved State program must be submitted to OSM for review as a program amendment. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State programs. Thus, any changes to the State program are not enforceable by the State as part of the approved State program until approved by the Director. In the oversight of the Wyoming program, the Director will recognize only statutes, regulations, and other materials approved by the Director, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Wyoming of only such provisions.

VII. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 (Reduction of Regulatory Burden) for actions related to approval or conditional approval of State regulatory programs, actions, and program amendments. Therefore, preparation of a regulatory impact analysis is not

necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 12550) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic

impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR 950

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 1, 1993.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T, the Code of Federal Regulations is amended as set forth below.

PART 950—WYOMING

1. The authority citation for part 950 continues to read as follows:

Authority: Pub. L. 95-87, Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*).

2. Section 950.15 is amended by adding paragraph (p) to read as follows:

§ 950.15 Approval of regulatory program amendments.

* * * * *

(p) With the exception of the LQD Rule at appendix B, section E, concerning exceptions from reporting migrating and wintering bald eagles or migrating peregrine falcons, the following provisions of the laws, rules and regulations of the Wyoming Department of Environmental Quality—Land Quality Division relating to coal exploration and coal mining and reclamation operations, as submitted on July 8, 1992, and as modified and clarified on January 11, 1993, are approved effective October 7, 1993: LQD Rules, chapter II, section 3(b)(iv)(B), chapter IV, section 3(o)(iv), and appendix B, "Wildlife Monitoring Requirements for Surface Coal Mining Operations."

3. In Section 950.16, paragraph (aa) is added to read as follows:

§ 950.16 Required program amendments.

* * * * *

(aa) By December 6, 1993, Wyoming shall submit revisions to the LQD Rules at appendix B, section E, to remove the language "[e]xcept migrating and wintering bald eagles or migrating peregrine falcons".

[FR Doc. 93-24622 Filed 10-6-93; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AD-FRL-4785-8]

Approval and Promulgation of State Implementation Plans; Establishment of Due Date for Sulfur Dioxide SIP for the Secondary NAAQS for East Helena, MT

AGENCY: Environmental Protection Agency (EPA).

ACTION: Deadline for SIP submittal.

SUMMARY: EPA hereby gives notice that it is approving the request by the State of Montana for the full three years allowed by section 172(b) of the Clean Air Act, as amended in 1990, (Act) for submittal of the State Implementation Plan (SIP) for the East Helena area to attain and maintain the sulfur dioxide (SO₂) secondary National Ambient Air Quality Standard (NAAQS).

DATES: The SIP revision for the East Helena area for the secondary SO₂ NAAQS will be due November 15, 1993.

FOR FURTHER INFORMATION CONTACT: Meredith Bond, U.S. Environmental Protection Agency, Region VIII, Air Programs Branch, 999 18th Street, Suite 500, Denver, Colorado 80202-2466, (303) 293-1764

SUPPLEMENTARY INFORMATION:

I. Background

By operation of law upon enactment of the 1990 Clean Air Act Amendments ("1990 Amendments"), the East Helena area was designated nonattainment with respect to the primary and secondary SO₂ NAAQS on November 15, 1990. Section 191 of the Clean Air Act provides that any state lacking an approved SIP for an area designated nonattainment with respect to the national primary ambient air quality standard for SO₂ must submit a plan meeting the requirements of the amended Act within 18 months of enactment of the amendments. The Act is silent as to a specific deadline for submittal of a plan for the secondary SO₂ NAAQS. Section 172(b), however, provides generally that the Administrator shall establish a schedule for plan submission for the secondary NAAQS, but that such schedule may extend no longer than three years from the date of nonattainment designation. Hence, the schedule for submitting the secondary SO₂ NAAQS SIP could extend no longer than November 15, 1993.

In the General Preamble for the Implementation of Title I of the 1990

Amendments (57 FR 13498, April 16, 1992), the Administrator did establish a SIP submittal schedule for those areas designated nonattainment with respect to both the primary and secondary SO₂ NAAQS. The preamble states, "[a]lthough the law allows up to three years for SIP submittal, because the level of control (for the secondary SO₂ NAAQS) is no more difficult to establish than for the primary NAAQS, and absent compelling justification by a State, EPA will require SIPs for those areas within 18 months of nonattainment designation." 57 FR 13546. In other words, the secondary SO₂ NAAQS SIP was to be submitted at the same time as the SIP for the primary SO₂ NAAQS unless justification was provided for a later submittal.

The State of Montana has provided justification that, for the East Helena area, the assumption that the secondary SO₂ NAAQS and primary SO₂ NAAQS require the same level of control does not hold true. The State has provided evidence that attainment of the secondary SO₂ three-hour NAAQS will require significant emission reductions, beyond what is required for attainment of the primary SO₂ 24-hour and annual NAAQS. Montana plans to conduct additional modeling to determine more precisely what emission reductions are necessary for attaining the secondary SO₂ NAAQS.

II. Justification Evidence

The ASARCO Incorporated (Asarco) primary lead smelter is the only major source of SO₂ emissions in the East Helena area. The company, in accordance with EPA and State guidance, commissioned dispersion modeling studies which predict the ambient impacts of SO₂ emissions from the Asarco smelter. The modeling studies were conducted for the typical emissions scenario as well as an emissions scenario which demonstrates compliance with the primary SO₂ NAAQS. The control strategies employed in this latter scenario consist of production and process limitations that Asarco plans to put into place with the primary SO₂ NAAQS SIP.

The modeling results show that emissions must be reduced 35 percent further (beyond those reductions to achieve the primary SO₂ NAAQS, as in the second scenario discussed above) in order to achieve compliance with the secondary SO₂ NAAQS. These substantial emissions reductions cannot reasonably be achieved through production or process changes. If production were reduced by 35 percent from current levels, Asarco estimates that annual revenue would be reduced

by more than \$12.4 million. Asarco contends that such a radical reduction in revenue would make the continued operation of the East Helena plant economically infeasible. The only other alternative would be to install new pollution control equipment.

Although EPA cannot confirm the projected level of revenue loss, we believe that the economic impact on both the industry and the community of East Helena would be significant. Therefore, EPA agrees with the State and Asarco that the only feasible way to meet the secondary SO₂ NAAQS, based on the available modeling results, would be to install new air pollution control equipment or new process technology.

This evidence demonstrates that the control measures required to meet the secondary SO₂ NAAQS in East Helena, MT, are much more extensive than those needed to meet the primary SO₂ NAAQS. EPA believes that the State has provided sufficient grounds for granting the full three years allowed under section 179(b) of the Act for submittal of this SIP.

III. Requirements for SIP

This notice granting the full three years for submittal of the East Helena, MT, secondary SO₂ NAAQS SIP requires Montana to submit a SIP revision no later than November 15, 1993. If the State does not submit a complete SIP by November 15, 1993, EPA may make a finding of failure to submit a SIP by the required date at that time. Any control strategies adopted and implemented as part of this SIP revision must provide for attainment and maintenance of the secondary SO₂ NAAQS as expeditiously as practicable.

IV. Final Action

This notice does not constitute a final agency action that is ripe for judicial review. EPA's action is a first step in an administrative process that will not be sufficiently concrete for judicial resolution until additional action is taken by EPA on a plan submittal by the State of Montana.

The 60-day time period for filing a petition for review of this action under section 307(b) of the CAA is tolled until EPA makes the action ripe by taking additional action in reliance on it, such as imposing sanctions on the State of Montana for failure to submit a SIP revision or promulgating approval of a SIP revision. A time limitation on petitions for judicial review can only run against challenges ripe for review.

List of Subjects in 40 CFR Part 52

Air pollution control, Sulfur dioxide.

Authority: Sections 101, 107, 110, 172(b) and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7401, 7407, 7410, 7502 and 7610(a)).

Dated: September 24, 1993.

Jack W. McGraw,

Acting Regional Administrator.

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BILLING CODE: 6560-50-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6998

[CA-940-4210-06; CAS 052887]

Partial Revocation of Public Land Order No. 2460; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes a public land order insofar as it affects 440 acres of public land withdrawn for the Temblor National Cooperative Land and Wildlife Management Area. The land is no longer needed for this purpose. The revocation is needed to allow the land to be exchanged under section 206 of the Federal Land Policy and Management Act of 1976. This action will open the land to the non-mineral public land laws unless closed by overlapping withdrawals or temporary segregations of record. The land has been and will remain open to mining and mineral leasing.

EFFECTIVE DATE: November 8, 1993.

FOR FURTHER INFORMATION CONTACT: Viola Andrade, BLM, California State Office, 2800 Cottage Way, Sacramento, California, 95825, 916-978-4820.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Public Land Order No. 2460, which withdrew public land for the Temblor National Cooperative Land and Wildlife Management Area, is hereby revoked insofar as it affects the following described land:

San Bernardino Meridian

T. 11 N., R. 24 W.,

Sec. 8, SE $\frac{1}{4}$ NE $\frac{1}{4}$ and E $\frac{1}{2}$ SE $\frac{1}{4}$;

Sec. 9, S $\frac{1}{2}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$, and W $\frac{1}{2}$ SE $\frac{1}{4}$.

The area described contains 440 acres in Kern County.

2. At 10 a.m. on November 8, 1993, the land will be opened to the operation of the non-mineral public land laws, subject to valid existing rights, the provisions of existing withdrawals,

other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 10 a.m. on November 8, 1993, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

Dated: September 27, 1993.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 93-24684 Filed 10-6-93; 8:45 am]

BILLING CODE 4310-40-M

43 CFR Public Land Order 6999

[NM-010-4210-06; NMNM 86711]

Withdrawal of Public Lands and Federal Minerals for Azabache Station, Big Bear Mesa, and Jones Canyon Archeological Sites; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 800 acres of public lands from surface entry and mining, and 240 acres of federally reserved mineral interests underlying private surface estate from mining, for a period of 20 years, for the Bureau of Land Management to protect the archeological, historical, geological, and recreational values of Azabache Station, Big Bear Mesa, and Jones Canyon sites. The lands have been and remain open to mineral leasing.

EFFECTIVE DATE: October 7, 1993.

FOR FURTHER INFORMATION CONTACT: Debby Lucero, BLM Rio Puerco Resource Area, 435 Montano NE, Albuquerque, New Mexico 87107, 505-761-8700.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Subject to valid existing rights, the following described public lands are hereby withdrawn from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C. Ch. 2 (1988)), but not from leasing under the mineral leasing laws, to protect three Bureau of Land Management archeological sites:

New Mexico Principal Meridian

T. 15 N., R. 4 W.,

Sec. 25, W $\frac{1}{2}$.

T. 16 N., R. 5 W.,

Sec. 15, W $\frac{1}{2}$ NE $\frac{1}{4}$.

T. 19 N., R. 2 W.,

Sec. 26, NW $\frac{1}{2}$, and E $\frac{1}{2}$ SW $\frac{1}{4}$;

Sec. 27, NE $\frac{1}{4}$.