§ 520.182 [Amended]

2. Section 520.182 *Bicyclohexylammonium fumagillin* is amended in paragraph (b) by removing "000074" and adding in its place "059620".

Dated: January 14, 1993.

Robert Furrow,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 93-1441 Filed 1-21-93; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Milbemycin Oxime

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 Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplemental NADA provides for use of milbemycin oxime tablets in dogs for removal and control of adult roundworm and whipworm infections in addition to the existing approved use for prevention of heartworm disease and control of hookworm infections.

EFFECTIVE DATE: January 22, 1993.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8614.

SUPPLEMENTARY INFORMATION: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, filed supplemental NADA 140-915 which provides for use of 2.3-, 5.75-, 11.5-, and 23.0-milligram Interceptor® (milbemycin oxime) tablets for use as an anthelmintic in dogs. The supplemental NADA provides for use of the product for removal and control of adult *Toxocara canis* (roundworm) and *Trichuris vulpis* (whipworm) infections in dogs over 8 weeks of age. The product is currently approved for prevention of heartworm disease caused by *Dirofilaria immitis* and control of hookworm infections caused by *Ancylostoma caninum*. The supplemental NADA is approved as of December 29, 1992, and the regulations are amended by revising 21 CFR 520.1445(c)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 supplemental NADA approval qualifies for 3 years of marketing exclusivity for the new indications beginning December 29, 1992, because new clinical or field investigations (other than bioequivalence or residue studies) conducted by the sponsor were required for the approval.

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.

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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.1445 is amended by revising paragraph (c)(2) to read as follows:

§ 520.1445 Milbemycin oxime tablets.

* * * * *

(c) * * *

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by *Toxocara canis* and whipworm infections caused by *Trichuris vulpis* in dogs.

* * * * *

Dated: January 8, 1993.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93-1440 Filed 1-21-93; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 4

[T.D. ATF-335; Ref: Notice Nos. 739, 744]

RIN 1512-AB09

Labeling of Bulk Process Sparkling Wine (90F167P)

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

ACTION: Treasury decision, final rule.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is amending the regulations in 27 CFR part 4 to permit the use of the phrases "fermented outside the bottle," "secondary fermentation outside the bottle," "secondary fermentation before bottling," "not fermented in the bottle," or "not bottle fermented," as alternatives to "bulk process" to further describe sparkling wine produced by fermentation in a large closed container. The Director may authorize the use of other or additional descriptive terms to further describe sparkling wine made by this process upon a determination by the Director that such term adequately informs the consumer about the method of production of the sparkling wine. The term "charmat method" or "charmat process" may be used as additional information. In addition, ATF is establishing guidelines with respect to legibility requirements applicable to the optional designation on sparkling wine labels.

EFFECTIVE DATE: July 22, 1993.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20091 (202-927-8230).

SUPPLEMENTARY INFORMATION:

I. Background

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), vests broad authority in the Director of ATF, as a delegate of the Secretary of the Treasury, to prescribe regulations intended to prevent deception of the consumer, and to

provide the consumer with adequate information as to the identity and quality of the product. The legislative history of the FAA Act shows that Congress intended to grant broad rulemaking authority to ensure that labels on alcoholic beverages provide consumers with adequate information about the product. In hearings before the House Ways and Means Committee on H.R. 8539, 74th Cong., 1st Sess., Joseph Choate, Director of the Federal Alcohol Control Administration, stated with respect to regulations to be promulgated.

> Those regulations were intended to insure that the purchaser should get what he thought he was getting, that representations both in labels and in advertising should be honest and straightforward and truthful. They should not be confined, as the pure-food regulations have been confined, to prohibitions of falsity, but they should also provide for the information of the consumer, that he should be told what was in the bottle, and all the important factors which were of interest to him about what was in the bottle. (Record of hearing, June 19 and 20, 1935, p. 10.)

Regulations which implement the provisions of section 105(e), as they relate to wine, are set forth in title 27, Code of Federal Regulations (CFR), part 4. Subpart C of part 4 sets forth the standards of identity for wine for labeling and advertising purposes. The current labeling regulations, 27 CFR 4.21(b)(2), provide that "champagne" is a type of sparkling light wine which derives its effervescence solely from the secondary fermentation of the wine in bottles of not greater than 1 gallon capacity, and which possesses the taste, aroma, and other characteristics attributed to champagne as made in the Champagne District of France. Pursuant to § 4.34(a), the type designation "champagne" may appear on the label in lieu of the class designation "sparkling wine."

Section 4.21(b)(3) provides that a sparkling light wine which derives its effervescence from the secondary fermentation of the wine in containers larger than a 1 gallon bottle, and having the taste, aroma, and characteristics generally attributed to champagne may, in addition to but not in lieu of the required class designation "sparkling wine," be further designated as "champagne style" or "champagne type" or "American (or New York State, California, etc.) champagne-bulk process." As further specified in the regulation:

> * * * all the words in such further designation shall appear in lettering of substantially the same size and such lettering shall not be substantially larger than the words "sparkling wine."

II. Amendment of § 4.21(b)(3)

As indicated, sparkling wines are made naturally effervescent by secondary fermentation in closed containers. "Champagne" is a type of sparkling wine that begins as a table wine to which yeast and sugar are added. This induces a secondary fermentation. The wine is then placed in bottles which are closed securely to withstand the pressure that develops as a result of the fermentation. This secondary fermentation accounts for the bubbles in the wine. In producing bulk process sparkling wine having the characteristics generally attributed to champagne, the secondary fermentation occurs in large (sometimes as much as 35,000 gallons) glass-lined containers instead of in individual bottles.

Historically, it has been ATF's position that there is a difference in identity between champagne produced by secondary fermentation within a bottle and sparkling wine having the characteristics generally attributed to champagne which has been produced by secondary fermentation in a container larger than a 1 gallon bottle. As such, ATF has required that the labels of these products make a distinction between the two methods of secondary fermentation. The most commonly used designation that is currently allowed in the regulations to describe the method by which sparkling wine is produced by fermentation in a large closed container is "bulk process."

Recently, several domestic producers of bulk process sparkling wines requested greater flexibility in the labeling of sparkling wines. ATF agrees that greater flexibility in the labeling of sparking wine where secondary fermentation occurs outside the bottle is appropriate. As previously mentioned, the purpose of the labeling provisions of the FAA Act is to provide the consumer with adequate information as to the identity and quality of the product. ATF believes that there are other terms which accurately describe and explain the production process to the consumer in language which is simple and easy to understand.

In addition, after reviewing numerous certificates of label approval for bulk process sparkling wines having the characteristics generally attributed to champagne, ATF had observed that on a number of labels the word "champagne" appeared more prominently and conspicuously than the words "bulk process" and the mandatory designation "sparkling wine." While these labels are in compliance with current regulations, since the word "champagne" is not substantially larger than the words "sparkling wine," there was concern that such labels could result in consumer confusion regarding the true identity of the product. Accordingly, ATF considered amending § 4.21(b)(3) in order to provide specific guidelines for placement and type size requirements applicable to the optional designation on bulk process sparkling wine labels.

III. Notice No. 739

On May 5, 1992, the Bureau published a notice in the **Federal Register** (Notice No. 739, 57 FR 19267) proposing to amend the wine regulations to permit the use of other phrases as alternatives to the phrase "bulk process" to further describe sparkling wine produced by fermentation in a large closed container. ATF also proposed to permit the use of the term "charmat method" as additional information to describe this process. The Bureau also proposed to establish specific standards with respect to placement and type size requirements applicable to the optional designation on sparkling wine labels. The specific proposals will be discussed below.

The comment period for Notice No. 739, initially scheduled to close on July 6, 1992, was extended until August 5, 1992, with the publication of Notice No. 744 (July 2, 1992, 57 FR 29456).

A. Wording and Placement

In Notice No. 739 ATF proposed to amend the regulations to permit bulk process sparkling wine having the characteristics generally attributed to champagne to be further designated as (1) "champagne style" or (2) "champagne type" or (3) "champagne," together with an appropriate appellation of origin disclosing the true place of origin of the wine, such as "American," "New York State," "Napa Valley," or "Chilean". Such further designation would be in addition to but not in lieu of the class designation "sparkling wine." The proposed regulations require that the appellation of origin immediately precede the word "champagne" on the same line or the immediately preceding line.

As it relates to the third further designation, (3) above, the proposed regulations required that one of the following terms appear together with the word "champagne:" "bulk process," "fermented outside the bottle," "secondary fermentation outside the bottle," "not fermented in the bottle," or "not bottle fermented." The term must immediately follow the word

"champagne" on the same line or the immediately following line.

In addition, in Notice No. 739 ATF proposed to allow the use of the term "charmat method" (named after the Frenchman who developed the bulk process technique in the early 1900s) as additional information to describe this process, provided it appears immediately before or after one of the previously mentioned phrases.

All the words in such further designation must appear together without any intervening graphics, words, etc. In the case of the third further designation, however, a mark of some sort (e.g., a dash) may appear between the word "champagne" and the remainder of the designation as, for example, "American champagne-fermented outside the bottle."

B. Size of Type

In reviewing approved labels for bulk process sparkling wines, ATF observed that the word "champagne" often appeared more prominently and conspicuously than the words "bulk process" and "sparkling wine." Initially, ATF was concerned that consumers may erroneously conclude that the product is bottle fermented "champagne," rather than sparkling wine having the characteristics generally attributed to champagne that has been fermented in a large closed container.

Section 4.21(b)(3) currently provides that all the words in the further designation must appear "in lettering of substantially the same size and such lettering shall not be substantially larger than the words 'sparkling wine.'" There seemed to be some confusion in the industry as to what is meant by the requirement that all of the words in the further designation must be of "substantially the same size." Similarly, the requirement that the further designation be in lettering not "substantially larger than the words 'sparkling wine'" appeared to be a less than adequate standard as to the differences in type sizes which are allowable. In order to address these problems, ATF proposed more specific guidelines for type size requirements.

Specifically, the Bureau proposed that on labels of bulk process sparkling wine, all the words in the further designation, including the appellation of origin, shall appear in lettering that is not smaller than the word "champagne" by more than 1 millimeter. In addition, the proposal provided that all the words in the further designation, including the word "champagne," as well as the optional term "charmat method," must appear in lettering that is not larger than the words "sparkling wine" by more than 1 millimeter.

C. Unqualified Use of the Word "Champagne"

In reviewing approved labels for bulk process sparkling wines, ATF also found that occasionally the unqualified word "champagne" appeared on the neck and back labels, while the entire optional designation set forth in the regulations appeared on the brand label. ATF saw the prominent display of the word "champagne," without any further qualification, as potentially misleading to the consumer as to the origin and method of production of the sparkling wine. On the other hand, the word "champagne" might be used as part of an explanatory text, usually on the back label, which is not misleading because of its context. For example, the explanatory text might not use the exact wording of the optional designation as set forth in the regulations, but it might set forth, in different language, the origin and method of production of the sparkling wine at issue.

Thus, ATF proposed that the word "champagne" could only appear on a label of bulk process sparkling wine where it was qualified by a further designation, in accordance with proposed § 4.21(b)(3) (i), (ii) and (iii), or where the word appeared as part of an explanatory text which the Director found was not misleading as to the origin or method of production of the sparkling wine. It was contemplated that this proposal would allow industry members to retain some flexibility in the use of the term "champagne" as part of an explanatory text given as additional information on the label, while ensuring that the consumer would not be misled as to the origin or method of production of the sparking wine.

D. Effective Date of Final Rule

Finally, in order to provide the industry with sufficient time to make label revisions, ATF proposed that any regulations issued pursuant to a final rule would become effective 1 year from the date of publication in the **Federal Register**.

IV. Analysis of Comments

In response to Notice Nos. 739 and 744, the Bureau received 60 comments. Most of the comments were submitted by industry members on behalf of producers of both bottle fermented and bulk fermented sparkling wines.

The majority of comments came from producers of bottle fermented sparkling wine. These comments were generally supportive of the four phrases proposed by the Bureau as alternatives to the phrase "bulk process" to further describe sparkling wine produced by fermentation in a large closed container. One commenter noted ATF's longstanding position that bottle fermented sparkling wine and bulk process sparkling wine are different products and that "the mandatory information on their labels should enable consumers to readily distinguish between the two."

In general, these comments also favored the proposal to establish specific placement and type size requirements for the further designation on labels of bulk process sparkling wines. However, many of the commenters believed that the proposal did not go far enough, and that the regulations should also require that all the words in the further designation, including the word "champagne," appear in the same style of type, in the same color, and on the same background. In addition, many of these commenters believed that the proposed phrase "charmat method" was misleading, in that consumers did not understand the term. Some concern was also expressed that consumers seeing a product labeled as "charmat" might be confused as to the origin of the sparkling wine. Finally, several comments suggested that the final rule should take effect within 6 months of publication.

ATF also received several comments from producers of bulk process sparkling wine. In general, these comments tended to be critical of the proposal. The comments objected to the proposed alternative phrases, as well as to the existing term "bulk process." The commenters stated that it was their belief that these terms conveyed negative connotations to the consumer. One commenter suggested an alternative phrase, "naturally fermented before bottling."

Furthermore, these commenters argued that most consumers are not interested in knowing about the production method used to make the sparkling wine, and that consumers perceive bulk process champagne to be "champagne"; therefore, sparkling wine produced by secondary fermentation in a large closed container should be entitled to use the term "champagne" without further qualifications. Assuming that a distinction on the label was required, these commenters favored using the phrase "charmat method" by itself on the label. They believe this term conveys accurate information about the production process, without any of the negative connotations of the phrases proposed in the notice.

Regarding the Bureau's proposals concerning type size and placement requirements for the further designation, one commenter stated that producers of bulk process sparkling wine should not be subject to extraordinary lettering size requirements or word placement restrictions. According to the commenter, such restrictions are unnecessary and would result in label clutter.

V. Discussion—Final Rule

ATF and its predecessor agencies have historically held that "champagne" is a type of sparkling wine produced by secondary fermentation within a bottle. This interpretation is based on traditional usage of the term. Extensive research indicates that the word "bottle" has been used to refer to glass containers of not greater than 1 gallon capacity.

Prior to enactment of the FAA Act, other Federal agencies had occasion to rule on the meaning of the term "champagne." In Food Inspection Decision (F.I.D.) 212, dated July 19, 1934, the Department of Agriculture ruled on use of the term "champagne" under the Federal Food and Drugs Act. As stated in the ruling, the term "champagne" could not be used on labels of sparkling wine unless the product was made by the same process as champagne made in the Champagne district of France. The Department referred to F.I.D. 212 in responding to an industry inquiry regarding the labeling of sparkling wine produced by secondary fermentation in large closed containers (vats). By letter dated January 14, 1935, the Department stated that the term " 'Champagne' * * * definitely implies that the secondary-fermentation has taken place in the bottle."

The same position was subsequently taken by the Federal Trade Commission (FTC) in a 1935 complaint filed against a domestic winery for misrepresenting their bulk process sparkling wines as "champagne." As stated in the FTC complaint,

> For a long period of time the term "champagne", when used in connection with wines has had and still has a definite significance and meaning * * * (wine) made sparkling by natural fermentation, which fermentation is completed in the bottle; * * *

On March 25, 1935, ATF's predecessor agency, the Federal Alcohol Control Administration (FACA), issued regulations providing that "champagne" was a type of sparkling wine produced by fermentation within a bottle (Misbranding Regulations, Series 6, Article II, Class 3(b)). The word "bottle," as defined in the regulations, referred to a container having a capacity not in excess of 1 gallon. Sparkling wine produced by secondary fermentation in a container larger than a bottle could be labeled as "champagne," provided the term was further qualified by the statement "Secondary Fermentation in Bulk."

After enactment of the FAA Act, the Federal Alcohol Administration (FAA) promulgated regulations containing standards of identity for wine. The issue of the labeling of champagne had been extensively discussed in the hearings held prior to the issuance of the regulations. In the press release announcing the promulgation of the regulations, the FAA stated that "(t)he testimony with respect to foreign and domestic champagne indicated that both from the point of view of the consumer and on the question of process a clear distinction was necessitated between sparkling wines produced by bottle fermentation and sparkling wines otherwise produced."

Consequently, the regulations issued in 1935 allowed the use of the term "champagne" on labels of sparkling wines produced by bottle fermentation, which had the taste, aroma, and other characteristics of champagne as produced in the champagne district of France. A sparkling wine not conforming to the prescribed standard for champagne, i.e., a wine produced by secondary fermentation in a large container, but having the taste, aroma, and characteristics generally attributed to champagne could be further designated as "Champagne style," "Champagne type," or "American (or New York State, California, etc.) Champagne—Bulk process." Such further designation would be in addition to but not in lieu of the class designation "Sparkling wine."

Thus, ATF and its predecessor agencies have consistently held that there is a difference in identity between champagne produced by secondary fermentation within the bottle and sparkling wine having the characteristics generally attributed to champagne which has been produced by secondary fermentation in a container larger than a 1 gallon bottle. This "difference" is not in reference to the taste, aroma, or other characteristics (e.g., stable foam, size of bubbles, etc.) of the finished product since, by regulation, both bottle and bulk fermented champagne must possess the taste, aroma, and other characteristics generally attributed to champagne as made in the champagne district of France. Rather, the "difference" is in regard to the standard of identity for "champagne," i.e., secondary fermentation must take place within a glass container of not greater than 1 gallon capacity. If the secondary fermentation is not within the bottle, the sparkling wine cannot be labeled as "champagne" without further qualification.

Thus, for more than 55 years ATF and its predecessor agencies have held that if the sparkling wine has the taste, aroma, and other characteristics generally attributed to champagne, but the secondary fermentation has taken place in a container larger than a 1 gallon bottle, the product may be labeled as "champagne," provided there appears along with it a qualifying statement which informs the consumer that the sparkling wine was not produced by secondary fermentation in a bottle.

A. Qualifying Statements

One comment submitted by several producers of bulk process sparkling wine challenged the basis for the longstanding distinction in the labeling of champagne, stating that technological advances since the 1930s had eliminated the need for distinguishing between bulk process and bottle fermented sparkling wines. As a result, "(c)hampagne makers using the charmat (bulk) process are today able to craft the characteristics they want in their champagne, including those commonly associated with bottle-fermented champagnes." The comment suggested that there was no chemical difference between the two products, and that consumers could not distinguish the products by taste. In support of that argument, a producer of bulk process sparkling wine submitted the results of a blind taste test in which consumers preferred a bulk process sparkling wine over two bottle fermented champagnes, and were unable to identify which sparkling wines were produced by which process.

The producers of bulk process sparkling wine also argued that consumers don't consider production process when buying champagne. In support of this argument, one commenter submitted the results of a consumer survey which indicated that very few consumers mentioned the method of production as an important factor in their purchase of champagne. More important factors were taste, price, and brand name. In regard to this last factor, when consumers were asked to name a brand of champagne, the brand most frequently named was one produced by the bulk process method. According to the commenter, this indicates that consumers perceive bulk process champagne as "champagne"

and, therefore, the need for a distinction in labeling between the two production processes no longer exists.

However, one commenter representing importers of bottle fermented sparkling wines also included the results of a consumer survey. The results of that survey indicated that nearly half the sparkling wine consumers could detect a difference in "mouth feel" between a bulk process and a bottle fermented sparkling wine, and the majority could correctly identify a bottle fermented product as being different from a bulk process product.

ATF finds that the consumer survey data presented by the two different commenters is conflicting and inconclusive. In any event, the basis for the regulation does not depend upon the proposition that bulk process sparkling wine tastes differently from bottle fermented champagne; as noted, the regulation requires that both types of wine possess the "taste, aroma, and other characteristics attributed to champagne as made in the champagne district of France."

Furthermore, ATF believes that, pursuant to its responsibilities under the FAA Act, a further qualification on the label is necessary to provide the consumer with information as to the identity of the product. That is, the consumer should be informed as to whether the product is "champagne" or a sparkling wine having the characteristics generally attributed to champagne. The additional qualifying statement is not intended to communicate any value judgment about the quality of the wine.

B. Wording

The majority of comments received in response to Notice No. 739 supported the Bureau's position that there is a difference in identity between champagne produced by secondary fermentation within a bottle and that produced by secondary fermentation in a closed container larger than a 1 gallon bottle. These commenters also supported the Bureau's proposed alternative phrases to "bulk process," as well as the proposal with respect to placement requirements applicable to the optional designation on sparkling wine labels.

As indicated, the producers of bulk process sparkling wines objected to the wording of the proposed alternative phrases. They believe that the phrases proposed by the Bureau would create a negative connotation in the minds of consumers, thus implying that a bulk process product is inferior in some way. In addition, these commenters believe that the proposed phrases do not accurately describe the method of production. Rather, they describe just one aspect of the process. On the other hand, the commenters believe that the term "charmat method" more accurately describes the complete production process.

The purpose of the labeling provisions of the FAA Act is to provide the consumer with adequate information as to the identity of the product. ATF believes that the alternative phrases proposed in Notice No. 739 alert consumers to the fact that the sparkling wine was not produced by bottle fermentation. Since this is the principal difference between bottle and bulk fermented champagne, ATF believes that it is appropriate to require a statement that focuses on this aspect of the production process. In addition, as one commenter pointed out:

> The label for virtually every bottle-fermented champagne (other than those produced in France currently on the market in the United States contains a reference to the fact that the product was 'bottle-fermented,' or made by the 'methode champenoise,' or 'fermented in this bottle.'

As can be seen, two of the three statements mentioned above are in reference to the container used for secondary fermentation. The term "methode champenoise" ("champagne method") also refers to the fact that the sparkling wine was produced by bottle fermentation. Since the proposed alternative phrases also refer to the type of container used for producing the sparkling wine, ATF believes that consumers will be adequately informed as to the identity of the product.

Furthermore, ATF does not believe that the proposed alternative phrases, or the existing term "bulk process," will have an adverse effect on the industry. As one commenter pointed out, "(t)oday, Charmat champagnes, * * * account for three-quarters of U.S. sparkling wine production and more than 50 percent of the sparkling wine market (including imports) in the United States." In addition, the Bureau would note that a qualifying descriptor has been required on labels of bulk process sparkling wines labeled as "champagne" since 1935.

Although it was suggested that the phrase "naturally fermented before bottling" be permitted as an alternative to the phrases proposed by the Bureau, ATF believes that the term "secondary fermentation before bottling" would be more informative to the consumer since it describes the method of production.

Therefore, as it relates to the wording of the further designation, upon the effective date of this final rule, bulk process sparkling wine having the characteristics generally attributed to champagne may, in addition to but not in lieu of the class designation "sparkling wine," be further designated as (1) "champagne style" or (2) "champagne type" or (3) "American (or New York State, Napa Valley, etc.) champagne," along with one of the following terms: "Bulk process," "fermented outside the bottle," "secondary fermentation outside the bottle," "secondary fermentation before bottling," "not fermented in the bottle," or "not bottle fermented."

ATF believes that there may be other terms which can be used as an appropriate description of sparkling wine produced by secondary fermentation outside the bottle. The purpose of the FAA Act is to ensure that the consumer is adequately informed about the identity of the product. Thus, this final rule also provides that the Director may authorize the use of additional terms on sparkling wine labels to further describe sparkling wine produced by fermentation in a large closed container, upon a determination by the Director that such terms adequately inform the consumer about the method of production of the sparkling wine. This issue will be discussed further in the section entitled *"Authorization of Alternative Terms."*

C. Placement and Size of Type

As it relates to the third further designation mentioned above, ATF proposed that the appellation of origin must immediately precede the word "champagne" on the same line or the immediately preceding line. In addition, the qualifying descriptor (e.g., "bulk process") must immediately follow the word "champagne" on the same line or the immediately following line. ATF also proposed that all the words in the further designation must appear together without any intervening graphics, words, etc.

Concerning type size requirements, the Bureau proposed that on labels of bulk process sparkling wine, all the words in the further designation, including the appellation of origin, shall appear in lettering that is not smaller than the word "champagne" by more than 1 millimeter. In addition, all the words in the further designation, as well as the optional term "charmat method," shall appear in lettering that is not larger than the words "sparkling wine" by more than 1 millimeter.

The proposals relative to type size and placement requirements for the optional designation were intended to provide industry members with specific guidelines concerning the labeling of

bulk process sparkling wine. The proposals were also intended to ensure that consumers were informed as to the true identity of the product. However, another goal of Notice No. 739 was to provide the industry with additional flexibility in the labeling of bulk process sparkling wines.

In general, the commenters representing importers and producers of bottle fermented sparking wines favored ATF's proposal to establish specific placement and type size requirements for the further designation. However, several commenters believed that the proposal did not go far enough, and that the regulations should also require that all the words in the further designation, including the word "champagne," appear in the same style of type, in the same color, and on the same background. These commenters were concerned that the restrictions on placement and type size did not go far enough in preventing labels which were misleading as to the method of production and origin of the wine.

On the other hand, concern was expressed that the Bureau's proposals with respect to type size and placement requirements applicable to the optional designation are overly restrictive, unnecessary, and would place an undue burden on the industry. As one commenter stated:

> (Production method information) should not be subject to extraordinary lettering size requirements or word placement restrictions. There is no need to clutter labels. If the goal of the mandatory labeling requirement is truly to inform, it is enough that the information be provided in a readable way * * * Charmat producers should not be handicapped by having to comply with label design restrictions that are not necessary in order to communicate information.

ATF did not receive any comments from consumers or consumer groups on this issue.

The purpose of the labeling provisions of the FAA Act is to provide the consumer with adequate information as to the identity of the product. In prescribing regulations ATF has the responsibility to ensure that the statutory goals are met, and that the consumer is "told (about) what was in the bottle." However, ATF does not believe that the regulations should be more restrictive on matters such as type size and placement than is necessary to meet the statutory goal. On the contrary, ATF believes that it should regulate only where necessary and to the extent necessary.

In the matter at hand, ATF's proposed amendment of the regulations was intended, in part, to provide the industry with additional flexibility in the labeling of bulk process sparkling wine. In addition, ATF proposed to establish specific guidelines with respect to placement and type size requirements with regard to the optional designation on sparkling wine labels to ensure that consumers were informed as to the identity of the sparkling wine product.

However, based on the comments received in response to Notice No. 739, ATF now believes that the proposed guidelines relative to type size and placement for the optional designation are too restrictive, and would place an undue burden on the industry. ATF agrees with the commenter who stated that "(i)f the goal of the mandatory labeling requirement is truly to inform, it is enough that the information be provided in a readable way."

On the other hand, ATF recognizes the concerns expressed by many of the commenters regarding the use of the word "champagne" on labels of bulk process sparkling wines. As mentioned, these commenters suggested that all the words in the further designation, including the word "champagne," should be required to appear in the same style of type, in the same color, and on the same background. While ATF believes that these factors should be considered in determining the acceptability of a label, the Bureau believes that a same style type, same color, and same background requirement is overly restrictive and unnecessary.

ATF believes that, for the most part, existing bulk process sparkling wine labels present the information required by the regulations in a way that is informative and not misleading. Rather than implement regulations which would require extensive changes in the labels for all of these products, ATF believes that it would be preferable to fashion a regulation which would prevent misleading labels, while still affording the industry flexibility in the matter of label design.

Therefore, this final rule provides that labels of bulk process sparkling wine shall be so designed that all the words in such further designation are readily legible under ordinary conditions and are on a contrasting background. In the case of the third further designation, ATF will consider whether the label as a whole provides the consumer with adequate information about the method of production and origin of the wine. In order to ensure that labels fairly provide the consumer with such relevant information, ATF will evaluate each label for legibility and clarity, based on such factors as type size and style for all components of the further designation and the optional term "charmat method," as well as the contrast between the lettering and its background, and the placement of information on the label. ATF will not approve any labels which depart from this purpose.

ATF believes that this regulation will provide the Bureau with adequate authority to prevent misleading sparkling wine labels, without mandating extensive and unnecessary changes in sparkling wine labels which are in compliance with the goals of the FAA Act.

D. Use of "Charmat Method"

In Notice No. 739 the Bureau proposed that the term "charmat method" (named after the Frenchman who developed the bulk process technique in the early 1900s) may be used as additional information to describe the bulk process, provided it appears immediately before or after one of the previously mentioned phrases.

Many commenters opposed the Bureau's proposal to allow the term "charmat method" as additional information on labels of bulk process sparkling wines. These commenters stated that the word "charmat" was meaningless to the consumer, and it could be easily confused with the term "champenoise," a word used by producers of bottle fermented sparkling wines to describe the method of production. On the other hand, several producers of bulk process sparkling wine argued that the term "charmat method" should be permitted on labels of bulk process sparkling wines as the sole descriptive qualifier of the term "champagne." It was also brought out in the comments that the term is broadly recognized in the technical literature as being an appropriate description of the bulk process.

ATF recognizes the historic usage of the term "charmat method" within the industry and in technical literature as an accurate description of sparkling wine produced by secondary fermentation in large closed container. One commenter provided several examples of the use of the term "charmat method" in wine textbooks, and other popular, professional, and technical wine literature. Because the term is recognized by wine experts as referring to secondary fermentation in bulk, ATF and its predecessor agencies have allowed the use of this term on sparkling wine labels for well over 35 years. However, the term has only been authorized as additional information to describe the method of production.

After considering the information provided in the comments, ATF has

concluded that the term "charmat method" should not be allowed as a sole descriptive qualifier of the word "champagne" on sparkling wine labels. While the comments provided evidence that the term was understood within the industry as referring to secondary fermentation in a tank, there was no evidence that the term had any widespread recognition among consumers. On the contrary, one commenter, representing the interests of importers of bottle fermented sparkling wines, submitted the results of a consumer survey which indicated that the opposite was true. Of the 482 consumers surveyed, 90 percent did not understand what the term "charmat method" meant. On the other hand, 77 percent of the consumers surveyed were able to correctly identify "bulk process" as a designation of sparkling wine fermented in a container and not in the bottle. Thus, the weight of the evidence supported the Bureau's conclusion that at this time, there is not enough consumer understanding of the term "charmat method" to justify allowing the term to appear on labels without qualification.

On the other hand, ATF does not agree that the use of the term "charmat method" as additional information on sparkling wine labels would be misleading as to the origin or identity of the wine. ATF believes that requiring one of the previously mentioned phrases to appear on the label, e.g., "fermented outside the bottle," will clarify the production process for consumers who might not be familiar with the meaning of the term "charmat method." Thus, the label will adequately inform the consumer that the sparkling wine was not produced by bottle fermentation. In addition, since an appellation of origin is required to appear on the label, ATF does not believe that there will be consumer confusion as to the origin of the wine. As such, ATF does not believe that it is necessary to require the term "charmat method" to appear immediately before or after one of the previously mentioned phrases. Such a requirement would be overly restrictive, and would place an undue hardship on the industry when designing their labels.

Thus, the final rule authorizes the use of the term "charmat method" as additional information on labels of bulk process sparkling wines. In addition, in re-examining certificates of label approval for these products, the Bureau has observed that the word "process" has been used as an alternative to the word "method," and the word "charmat" has often appeared together with the words "bulk process," as "charmat bulk process." Thus, in order to minimize the burden on the industry, this final rule also authorizes the use of the term "charmat process." In addition, the Bureau will continue to allow the word "charmat" to appear with the words "bulk process," as "charmat bulk process."

E. Authorization of Alternative Terms

When first requesting ATF approval for the use of alternative terms on sparkling wine labels, a major producer of sparkling wine made the argument that ATF should be able to issue an interpretive ruling authorizing the use of terms which were synonymous with the term "bulk process." The sparkling wine producer argued that such a result would be consistent with the intent of the regulations, and with ATF's statutory mandate to ensure that sparkling wine labels were informative to the consumer about the identity of the product. The existing regulations did not authorize ATF to allow the use of terms other than those specified in the regulations. Thus, rulemaking was initiated to authorize the use of certain alternate terms.

After considering the administrative record on this issue, ATF recognizes that, in addition to the five new terms authorized by this final rule, there may be other terms which can be used as an appropriate description of sparkling wine produced by secondary fermentation outside the bottle. Therefore, the final rule provides that the Director may authorize the use of additional terms on sparkling wine labels to further describe sparkling wine produced by fermentation in a large closed container, upon a determination by the Director that such terms adequately inform the consumer about the method of production of the sparkling wine. ATF believes that this provision will provide additional flexibility to sparkling wine producers, and will obviate the need for ATF to initiate rulemaking every time a winery wishes to use a new term to describe the method of production on a sparkling wine label.

Furthermore, after considering the comments submitted regarding the use of the term "charmat method," ATF has determined that while the current evidence does not support allowing this term as the sole descriptive qualifier of the word "champagne" on labels of bulk process sparkling wines, consumer understanding of winemaking terminology is not necessarily static. If it can be reasonably demonstrated that consumers recognize the term "charmat method," or any similar term, as referring to a sparkling wine produced by fermentation in a large closed container, and not in the bottle, then ATF shall open a rulemaking proceeding and consider such evidence as a primary factor in determining whether to specifically authorize the use of such terms as further designations on sparkling wine labels.

F. Unqualified Use of the Word "Champagne"

As stated previously, in reviewing approved labels for bulk process sparkling wines, ATF found that occasionally the unqualified word "champagne" appeared on the neck and back labels, while the entire optional designation set forth in the regulations appears on the brand label. ATF believed that the prominent display of the word "champagne," without any further qualification, could mislead the consumer as to the origin and method of production of the sparkling wine.

Thus, ATF proposed that the word "champagne" shall only appear on a label of bulk process sparkling wine where it is qualified by a further designation, or where the word appears as part of an explanatory text which the Director finds is not misleading as to the origin or method of production of the sparkling wine.

Many commenters supported the Bureau's proposal regarding the unqualified use of the word "champagne." However, in light of ATF's decision that the regulation does not need to prescribe the precise placement or type size of the further designation on the label, the Bureau believes that there is no longer a need to address this issue specifically in the regulation. The final rule gives ATF the authority to determine if the label as a whole is misleading, after considering factors such as the placement of information on the label. ATF would emphasize that if the word "champagne" is used on the label in such a manner that it tends to create a misleading or deceptive impression as to the actual identity of the product, the label will be rejected.

G. Effective Date of Final Rule

Several commenters suggested that the proposed year-long transition period for compliance with the final regulations was too long. ATF agrees with these comments, but wishes to ensure that the industry is provided with sufficient time to bring labels into compliance with this final rule. Therefore, the provisions of this Treasury decision will become effective 6 months from the date of publication in the **Federal Register**, and will apply

to sparkling wines bottled on or after that date.

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 geographical regions; and it will not have significant adverse affects 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.

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. Any benefit derived by a small proprietor from the new options provided in this rule will be the result of the proprietor's own promotional efforts and consumer acceptance of the specific product. No new reporting or recordkeeping requirements are imposed by this rule. Accordingly, a regulatory flexibility analysis is not required because this final rule is not expected (1) to have 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.

Paperwork Reduction Act

The collection of information contained in this final regulation has been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3504(h)) under control number 1512–0482. The estimated average burden associated with the collection of information in this final rule is 1 hour per respondent or recordkeeper.

Comments concerning the accuracy of this burden estimated should be directed to the Chief, Information Programs Branch, room 3110, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226 and to the Office of Management and Budget, Paperwork Reduction Project 1512–0482, Washington, DC 20503.

Disclosure

Copies of the notice of proposed rulemaking, all written comments, and this final rule will be available for public inspection during normal business hours at: ATF Public Reading Room, room 6480, 650 Massachusetts Avenue NW., Washington, DC.

Drafting Information

The author of this document is James P. Ficaretta, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, and Wine.

Authority and Issuance

27 CFR Part 4—Labeling and advertising of wine is amended as follows:

PART 4—[AMENDED]

Paragraph 1. The authority citation for 27 CFR Part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 4.21(b)(3) is revised to read as follows:

§ 4.21 The standards of identify.

* * * * *

(b) *Class 2; sparkling grape wine.*

* * *

(3)(i) A sparkling light wine having the taste, aroma, and characteristics generally attributed to champagne but not otherwise conforming to the standard for "champagne" may, in addition to but not in lieu of the class designation "sparkling wine," be further designated as:

(A) "Champagne style;" or

(B) "Champagne type;" or

(C) "American (or New York State, Napa Valley, etc.) champagne," along with one of the following terms: "Bulk process," "fermented outside the bottle," "secondary fermentation outside the bottle," "secondary fermentation before bottling," "not fermented in the bottle," or "not bottle fermented." The term "charmat method" or "charmat process" may be used as additional information.

(ii) Labels shall be so designed that all the words in such further designation are readily legible under ordinary conditions and are on a contrasting background. In the case of paragraph (b)(3)(i)(C) of this section, ATF will consider whether the label as a whole provides the consumer with adequate information about the method of production and origin of the wine. ATF will evaluate each label for legibility and clarity, based on such factors as type size and style for all components of the further designation and the optional term "charmat method" or "charmat process," as well as the contrast between the lettering and its background, and the placement of information on the label.

(iii) Notwithstanding the provisions of paragraphs (b)(3)(i)(A), (B) and (C) of this section, the Director may authorize the use of a term on sparkling wine labels, as an alternative to those terms authorized in paragraph (b)(3)(i) of this section, but not in lieu of the required class designation "sparkling wine," upon a finding that such term adequately informs the consumer about the method of production of the sparkling wine.

* * * * *

Signed: December 17, 1992.

Stephen E. Higgins,

Director.

Approved: January 13, 1993.

John P. Simpson,

Acting Assistant Secretary (Enforcement).

[FR Doc. 93–1386 Filed 1–21–93; 8:45 am]

BILLING CODE 4810–31–M

DEPARTMENT OF DEFENSE

Department of the Army

35 CFR Part 251

Panama Canal Employment System; Personnel Policy

AGENCY: Department of the Army, Defense.

ACTION: Final rule.

SUMMARY: This final rule amends part 251 of title 35, Code of Federal Regulations, to reflect changes to the Panama Canal Employment System (PCES). These changes will permit employees of non-Department of Defense (DOD) agencies attached to DOD agencies in the Republic of Panama, who have previously been ineligible to receive the recruitment and retention differential contained in the Panama Canal Act of 1979, to be eligible to receive such differential, provided such eligibility is agreed to between the employee's agency and DOD.

EFFECTIVE DATE: January 22, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Rhode, Jr., Assistant to the Chairman and Secretary, Panama Canal Commission, 2000 L Street NW., Washington, DC 20036–4996 (Telephone: 202–634–6441); Colonel W.

L. Mayew, Executive Officer to the Assistant Secretary of the Army (Civil Works), room 2E–569 The Pentagon, Washington, DC (Telephone: 703–697–9809); or Mr. Robert H. Rupp, Executive Director, Panama Area Personnel Board, Unit 2300, APO AA 34011 (Telephone in Corozal, Republic of Panama: 011–507–52–7890).

SUPPLEMENTARY INFORMATION: The Panama Canal Employment System (PCES) was established in section 1212 of the Panama Canal Act of 1979, Public Law 96–70, 93 Stat 464, 22 U.S.C. 3652. The PCES covers employees of the Panama Canal Commission and Department of Defense member agencies. Pursuant to 22 U.S.C. 3652(c) and (d), the President may amend any provision of the PCES, may exclude any employee or position from PCES coverage and may extend to any employee the rights and privileges provided to employees in the competitive service. This authority has been delegated through the Secretary of Defense and the Secretary of the Army to the Chairman of the Panama Area Personnel Board. These regulations are promulgated pursuant to this authority. Issuance of a notice of proposed rulemaking under 5 U.S.C. 553 is not necessary because the final rule pertains only to personnel of agencies covered by these regulations.

The final rule addresses the applicability of the PCES to employees of non-Department of Defense (DOD) agencies attached to DOD agencies in the Republic of Panama for the limited purpose of obtaining eligibility for the recruitment and retention differential provided for in section 1217 of the Panama Canal Act (22 U.S.C. 3657), provided such eligibility is agreed to between the employee's agency and DOD. The provisions of 35 CFR 251.31 and 251.32 which fix the specific eligibility requirements of the differential may be also made applicable to these employees. Similarly, the provisions of section 1218 (22 U.S.C. 3658) and of 35 CFR 251.25, which define basic pay, may be also made applicable. Previously, employees serving in these positions were ineligible for the aforementioned differential. This amendment will now give the employee's agency and DOD the flexibility to make the differential applicable to these non DOD employees assigned to DOD agencies in Panama provided the two agencies agree to do so.

This provision of the final rule does not affect the limited quarters allowance provided in 22 U.S.C. 3657a. As provided in 22 U.S.C. 3657a(d), a qualifying emplcyee is eligible for the quarters allowance regardless of participation in the PCES by the employer agency.

This final rule is not a major rule as defined in Executive Order 12291 of February 17, 1981. As required by the Regulatory Flexibility Act, it is certified that this final rule will not have a significant economic impact on a substantial number of small business entities. I certify that these proposed changes in regulations meet the applicable standards provided in sections 2(a) and (b)(2) of Executive Order No. 12778.

List of Subjects in 35 CFR Part 251

Panama Canal Employment System, Army Secretary Regulations, Personnel Policy.

Accordingly, 35 CFR Part 251 is amended as follows:

PART 251—REGULATIONS OF THE SECRETARY OF THE ARMY (PANAMA CANAL EMPLOYMENT SYSTEM)—PERSONNEL POLICY

1. The authority citation for Part 251 continues to read as follows:

Authority: 22 U.S.C. 3541–3701, E.O. 12173, 12215.

2. Section 251.4(a) is amended by removing "(g)" after the word "through" and inserting "(i)" in its place.

3. Section 251.4 is amended by adding paragraph (i) as follows:

§ 251.4 Adoption of Panama Canal Employment System by Department of Defense.

* * * * *

(i) Officers and employees of non-Department of Defense (DOD) agencies attached to DOD agencies in Panama are excluded from all the provisions of subchapter II and the regulations contained in this part and part 253 of this chapter, except that such employees may be covered by the provisions of sections 1217, 1217a, and 1218 of subchapter II and the regulations in §§ 251.25, 251.31 and 251.32 of this chapter, if coverage by said provisions is agreed to by the employee's agency and DOD and such coverage does not result in a benefit greater than that provided to DOD employees.

Dated: January 10, 1993.

M.P.W. Stone,

Chairman, Panama Area Personnel Board.

[FR Doc. 93–1308 Filed 1–21–93; 8:45 am]

BILLING CODE 3710–02–P

COPYRIGHT ROYALTY TRIBUNAL

37 CFR Chapter III

[Docket No. CRT 93–2–RM]

Modification of Rules of Agency Organization

AGENCY: Copyright Royalty Tribunal.

ACTION: Final rule.

SUMMARY: The Copyright Royalty Tribunal is amending its rule addressing the Composition of the Tribunal. The amendment adopts the Senate's June 13, 1990 amendment of chapter 8 of title 17, United States Code, to reduce the number of Commissioners on the Copyright Royalty Tribunal, to provide for lapsed terms and for other purposes.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Linda R. Bocchi, General Counsel, Copyright Royalty Tribunal, 1825 Connecticut Avenue NW., suite 918, Washington, DC 20009. (202) 606–4400.

SUPPLEMENTARY INFORMATION: On June 13, 1990, the Senate proceeded to consider the bill (S. 1272) to amend chapter 8 of title 17, United States Code, to reduce the number of Commissioners on the Copyright Royalty Tribunal, to provide for lapsed terms of such Commissions, and for other purposes, which had been reported from the Committee on the Judiciary.

In lieu of the fact that the revision is undertaken to incorporate a 1990 amendment by the Senate, the revised rule will become effective immediately.

Accordingly, § 301.3 of the Tribunal's Rules is amended in the manner set forth below:

List of Subjects in 37 CFR Part 301

Administrative practice and procedure, Freedom of Information Act, Sunshine Act.

PART 301—COPYRIGHT ROYALTY TRIBUNAL RULES OF PROCEDURE

1. The authority citation for part 301 continues to read as follows:

Authority: Chapter 8 of title 17, United States Code.

2. Section 301.3 is revised as follows:

§ 301.3 Composition of the Tribunal.

The Tribunal is composed of three Commissioners appointed by the President, by and with the advice and consent of the Senate. The term of office of any individual appointed as a Commissioner shall be seven years, except that a Commissioner may serve after the expiration of his or her term until a successor has taken office. Each Commissioner shall be compensated at

the rate of pay in effect for Level V of the Executive Schedule under section 5316 of title 5.

Dated: January 14, 1993.

Cindy Daub,

Chairman.

[FR Doc. 93–1354 Filed 1–21–93; 8:45 am]

BILLING CODE 1410–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1005

RIN 0991–AA75

Health Care Programs; Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100–93

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule and clarification.

SUMMARY: This final rule clarifies the scope and purpose of the exclusion authority provisions originally set forth in final rulemaking published in the Federal Register on January 29, 1992 (57 FR 3298). That final rule implemented the OIG sanction and civil money penalty (CMP) provisions established through section 2 and other conforming amendments in the Medicare and Medicaid Patient and Program Protection Act of 1987, and other statutory authorities. This clarifying document modifies the final rule to give greater clarity to the original scope of the authorities contained in 42 CFR part 1001. In addition, this rule is providing further clarification to the discovery provision set forth in part 1005 of the regulations.

EFFECTIVE DATE: This regulation is effective on January 22, 1993.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Inspector General, (202) 619–3270.

SUPPLEMENTARY INFORMATION:

I. Background

On January 29, 1992, we published in the Federal Register a final rule to implement a variety of OIG sanction and civil money penalty provisions established through section 2 and other conforming amendments in the Medicare and Medicaid Patient and Program Protection Act of 1987, along with certain additional provisions contained in the Consolidated Budget Reconciliation Act of 1985, the Omnibus Budget Reconciliation Act (OBRA) of 1987, the Medicare Catastrophic Coverage Act of 1988, OBRA 1989, and OBRA 1990 (57 FR 3298). Those final regulations were designed to protect program beneficiaries from unfit health care practitioners, and otherwise to improve the anti-fraud provisions of the Department's health care programs under titles V, XVIII, XIX and XX of the Social Security Act.

As a result of that final rule, 42 CFR part 1001 was amended to specifically set forth each type of exclusion, the basis or activity that would justify the exclusion, and the considerations that would be used in determining the period of exclusion. (In addition, through the revision and recodification of existing regulations, a new 42 CFR part 1005 was added to address various procedures that govern administrative hearings and subsequent appeals for all OIG sanction cases.)

Since publication of the final rule, we have become aware that an uncertainty exists with regard to the scope and applicability of the exclusion authorities set forth in part 1001 of the regulations. This final rule gives clarity to the original intent of the scope and applicability of existing exclusion authorities.

II. Revisions to 42 CFR 1001.1 and 1005.4

We are clarifying § 1001.1, Scope and purpose, to explicitly indicate that the exclusion provisions in 42 CFR part 1001 apply to and bind (1) the OIG in imposing and proposing program exclusions, and (2) the administrative law judges (ALJs), the Departmental Appeals Board (DAB) and federal courts in reviewing the imposition of exclusions by the OIG (or, where applicable, in imposing exclusions proposed by the OIG).

It has always been implicit that the circumstances for each program exclusion and the specified length for each exclusion (including the mitigating and aggravating circumstances) set forth in 42 CFR part 1001 would bind the OIG, ALJs and the DAB in all their decision making. Following the publication of the revised exclusion regulations on January 29, 1992, however, it has been brought to our attention that it could be possible to interpret part 1001 as applying only to the imposition of exclusions by the OIG, and not to the review of exclusions by ALJs, the DAB and federal courts. This is not the result intended by the Secretary or these regulations, and is inconsistent with the application of the prior regulations codified at 42 CFR part 1001 to program exclusions.

The regulatory provisions in 42 CFR part 1001 were promulgated in large part to add consistency and predictability to the overall process of imposing program exclusions. Were the Secretary to have so limited the applicability of these highly specific, substantive provisions set forth in part 1001, the effect of the regulations would be virtually nullified if interpreted as binding the OIG to their requirements while, at the same time, providing the ALJs with total discretion to disregard the regulatory requirements and review the OIG's imposition of exclusions as if there were no applicable regulatory standards.

In addition, we are also making a related change to the ALJs' authority in § 1005.4(c) to make clear that ALJs do not have the authority to find invalid or refuse to follow Federal statutes, regulations or Secretarial delegations of authority.

III. Technical Clarification to Section 1005.7

In addition, we are revising paragraph (e)(1) of § 1005.7, Discovery, to clarify that parties are not required to file a motion for a protective order as a condition precedent for withholding documents under a claim of privilege. The revised § 1005.7(e)(1) also specifically states that the parties are allowed to have the opportunity to file a motion for a protective order at any time during discovery.

As revised, § 1005.7(e)(1) deletes the unrealistic time frame for filing a motion for a protective order. The revised section gives the parties the option of filing a motion for a protective order at any time during the discovery process.

IV. Regulatory Impact Statement

Executive Order 12291 requires us to prepare and publish a final regulatory impact analysis for any regulation that meets one of the Executive Order criteria for a "major rule." In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601–612), unless the Secretary certifies that a final regulation would not have a significant economic impact on a substantial number of small entities.

As we indicated in the original final rule published on January 29, 1992, consistent with the intent of the statute, the amendments to 42 CFR chapter V, and this subsequent clarification, are designed to clarify departmental policy with respect to the imposition of exclusions, CMPs and assessments upon individuals and entities who violate the

statute. We continue to believe that the great majority of providers and practitioners do not engage in such prohibited activities and practices, and that the aggregate economic impact of these provisions should be minimal, affecting only those who have engaged in prohibited behavior in violation of statutory intent.

For this reason, we have determined that a regulatory impact analysis is not required. Further, we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a number of small business entities, and we have, therefore, not prepared a regulatory flexibility analysis.

V. Effective Date and Waiver of Proposed Rulemaking

Since this rulemaking is designed to clarify departmental policy already set forth in final regulations with respect to the imposition of exclusions, CMPs and assessments, we are waiving the proposed notice and public comment period in accordance with the exceptions to the Administrative Procedure Act (APA) set forth in 5 U.S.C. 553(b)(A). Specifically, 5 U.S.C. 553(b)(A) excepts "interpretative rules, general statements of policy or rules of agency organization, procedure or practice" from the notice and comment requirements under the APA. This regulation meets all three exceptions set forth in this section. It is an interpretative rule in that it interprets the application and scope of 42 CFR part 1001; it is a statement of Departmental policy with respect to the application of 42 CFR part 1001; and it is a rule of agency procedure in that it directs the ALJs and the DAB to apply 42 CFR part 1001 to their reviews of OIG exclusion decisions. Therefore, we believe that proposed notice and public comment for this rulemaking is unnecessary.

In addition, this document does not promulgate any substantive changes to the scope of the January 29, 1992 final rule, but rather seeks only to clarify the text of that rulemaking to better achieve our original intent. Since it is not substantive, we are issuing this clarifying regulation as a final rule to be effective immediately, rather than the usual 30-day delay required for substantive rules under 5 U.S.C. 553(d). This clarifying rule will apply to all pending and future cases under this authority.

List of Subjects

42 CFR Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicaid, Medicare.

42 CFR Part 1005

Administrative practice and procedure, Fraud, Penalties.

42 CFR chapter V is amended as set forth below:

A. 42 CFR part 1001 is amended as set forth below:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E) and (F), and 1395hh, and section 14 of Public Law 100–93 (101 Stat. 697).

2. Section 1001.1 is amended by designating the existing paragraph as paragraph (a), and by adding a new paragraph (b) to read as follows:

§ 1001.1 Scope and purpose.

* * * * *

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

B. 42 CFR part 1005 is amended as set forth below:

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

1. The authority citation for part 1005 continues to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

2. Section 1005.4 is amended by revising paragraph (c)(1) and republishing paragraph (c) introductory text to read as follows:

§ 1005.4 Authority of the ALJ.

* * * * *

(c) The ALJ does not have the authority to—

(1) Find invalid or refuse to follow Federal statutes or regulations or secretarial delegations of authority;

* * * * *

3. Section 1005.7 is amended by revising paragraph (e)(1) to read as follows:

§ 1005.7 Discovery.

* * * * *

(e)(1) After a party has been served with a request for production of documents, that party may file a motion for a protective order.

* * * * *

Dated: November 23, 1992.

Bryan B. Mitchell,

Principal Deputy Inspector General.

Approved: December 18, 1992.

Louis W. Sullivan,

Secretary.

[FR Doc. 93–1376 Filed 1–21–93; 8:45 am]

BILLING CODE 4150–04–M

FEDERAL MARITIME COMMISSION

46 CFR Parts 514, 580, 581 and 583

[Docket No. 92–37]

Financial Responsibility for Non-Vessel-Operating Common Carriers

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission ("FMC" or "Commission") is amending its regulations governing the financial responsibility requirements of Non-Vessel-Operating Common Carriers ("NVOCCs") in response to the Non-Vessel-Operating Common Carrier Act of 1991 ("1991 Act"). The 1991 Act amended section 23 of the Shipping Act of 1984 ("1984 Act"), to permit the Commission to accept—in addition to bonds—insurance or other surety as proof of an NVOCC's financial responsibility. The 1991 Act also deleted the $50,000 minimum amount for a bond previously prescribed by section 23. The final rule: (1) Specifies the conditions for accepting insurance and guaranties as evidence of an NVOCC's financial responsibility; (2) provides forms and procedures for accepting insurance and guaranties as evidence of an NVOCC's financial responsibility; (3) specifies standards for the acceptability of insurance companies and guarantors; and (4) specifies the amount and method of coverage.

EFFECTIVE DATE: February 22, 1993.

FOR FURTHER INFORMATION CONTACT: Austin L. Schmitt, Director, Bureau of Trade Monitoring and Analysis, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001, (202) 523–5787.

SUPPLEMENTARY INFORMATION: The Commission initiated this proceeding by an Advance Notice of Proposed Rulemaking ("ANPR") published in the