Field Office, P.O. Box 1838, 8001 Forbes Place (5285 Port Royal Road), room 201, Springfield, Virginia 22151–0838.

(d) *Action by the Office of Export Enforcement.* After the Office of Export Enforcement has been provided with the required narrative and supporting documentation, it will acknowledge the disclosure by letter, provide the person making the disclosure with a point of contact, and take whatever additional action, including further investigation, it deems appropriate. As quickly as the facts and circumstances of a given case permit, the Office of Export Enforcement may then take any of the following actions:

(1) Inform the person or firm making the disclosure that, based on the facts disclosed, it plans to take no action;

(2) Issue a warning letter;

(3) Issue a proposed charging letter pursuant to § 788.17(b) of this subchapter and attempt to settle the matter;

(4) Issue a charging letter pursuant to § 788.4 of this subchapter if a settlement is not reached; or

(5) Refer the matter to the United States Department of Justice for criminal prosecution.

(e) *Criteria.* For purposes of determining what administrative action to take and what sanctions, if any, to impose, the fact that a voluntary self-disclosure has been made will be a mitigating factor. OEE will take that factor into account along with other mitigating and aggravating factors when determining what, if any, administrative sanction it will impose. The factors that OEE will consider are in its sole discretion. Some of the factors are:

(1) The extent to which the purpose of the control is undermined by the transaction;

(2) Whether the transaction would have been authorized had proper application been made;

(3) The quantity and value in U.S. dollars of the commodities or technical data involved;

(4) Why the violations occurred. For example, the Office of Export Enforcement may consider whether the violations were intentional or inadvertent; the degree to which the person or firm responsible for the violation making the disclosure was familiar with the Regulations; and whether the violator was the subject of prior administrative or criminal action under the Act;

(5) Whether, as a result of the information provided, the Office of Export Enforcement is able to prevent any commodities or technical data exported illegally from reaching unauthorized persons or destinations;

(6) The degree of cooperation with the ensuing investigation;

(7) Whether the person or firm has instituted or improved an internal compliance program to reduce the likelihood of future violations.

(f) *Treatment of unlawfully exported commodities after voluntary self-disclosure.* (1) In accordance with § 772.7(b) of this subchapter, if commodities or technical data that are the subject of a voluntary self-disclosure were exported without the required license, no such license will be issued after the fact.

(2) Reexport authorization for commodities or technical data that are the subject of a voluntary self-disclosure and that have been exported contrary to the provisions of the Act or the regulations may be requested from the Office of Export Licensing in accordance with the provisions of part 774 of this subchapter. If the applicant for reexport authorization knows or has reason to know that the commodities or technical data are the subject of a voluntary self-disclosure, the request should state that a voluntary self-disclosure was made in connection with the export of the commodities for which reexport authorization is sought.

(3) Section 787.4(a) prohibits any person from taking certain actions with knowledge or reason to know that a violation of the Act or the Regulations has occurred. Any person who has made a voluntary self-disclosure has reason to believe that a violation may have occurred. However, for those commodities or technical data that are the subject of a voluntary self-disclosure, permission to take any of the actions set forth in § 787.4(a), which may otherwise be prohibited, may be requested from the Office of Export Licensing. The Office of Export Licensing's decision on any such request will be made in consultation with the Office of Export Enforcement. Requests for permission should be sent to the Office of Export Licensing at the following address: Office of Export Licensing, P.O. Box 273, Washington, DC 20044.

Dated: August 1, 1990.

Quincy M. Krosby,

Assistant Secretary for Export Enforcement.

[FR Doc. 90-18477 Filed 8-8-90; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. 84N-0036]

Removal of Regulation Regarding Sulfonamide-Containing Drugs for Use in Food-Producing Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing its regulation providing for interim marketing for drugs containing sulfamethazine, sulfaquinoxaline, sulfamerazine, sulfathiazole, sulfapyridine, or sulfanilamide for oral, injectable, intramammary, or intrauterine use in food-producing animals. After the removal of the regulation, any sulfanamide-containing drug product on the market intended for use in food-producing animals that is not the subject of an approved new animal drug application (NADA) will be in violation of the Federal Food, Drug, and Cosmetic Act (the act) and subject to regulatory action, unless covered by a statutorily-provided exception to the requirement of an NADA. The agency is taking this action following the publication in the **Federal Register** of September 15, 1988 (53 FR 35833), of a proposal to remove the regulation, and the publication in the **Federal Register** of July 5, 1984 (49 FR 27543), of a notice announcing plans to terminate interim marketing of the sulfonamide-containing drugs in question.

DATES: The removal of the regulation is effective November 7, 1990.

FOR FURTHER INFORMATION CONTACT: Philip J. Frappaolo, Center for Veterinary Medicine (HFV-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4940.

SUPPLEMENTARY INFORMATION:

I. Summaries of and Responses to Comments

In the **Federal Register** of September 15, 1988 (53 FR 35833) (corrected 53 FR 46976; November 21, 1988), FDA proposed to remove § 510.450 (21 CFR 510.450), which provides for interim marketing for drugs containing sulfamethazine, sulfaquinoxaline, sulfamerazine, sulfathiazole, sulfapyridine, or sulfanilamide for oral, injectable, intramammary, or intrauterine use in food-producing

animals. The agency also made available through publication of the proposed rule a finding of no significant impact and the environmental assessment under 21 CFR part 25. The history of § 510.450 is discussed in detail in the preamble to the proposed rule and in FDA's July 5, 1984 (49 FR 27543) (corrected August 7, 1984; 49 FR 31444), notice announcing plans for the termination of interim marketing and requesting that the sponsors of the above new animal drugs submit data, revised labeling, and other information necessary for approval of an NADA. The proposal provided 60 days for interested persons to comment. The agency received 48 comments on the proposal. Most of the comments were from veterinarians and other individuals; the balance of the comments were from drug sponsors and distributors, professional and trade associations, and a university. FDA's summaries of and responses to the comments follow:

1. Many comments, particularly those from individuals, argued that FDA should not remove sulfonamide-containing drugs covered by § 510.450 from the market, claiming that they are of benefit to veterinarians, livestock producers, the products' sponsors, and the public.

FDA advises that the removal of § 510.450 will not result in the removal from the market of sulfonamide-containing drugs in general, but only of those sulfonamide-containing drug products that are covered by § 510.450 and that are not the subject of approved NADA's. For all but six uses of the sulfonamide-containing products covered by § 510.450, there are sulfonamide-containing drug products with approved NADA's (see the finding of no significant impact and environmental assessment for revocation of 21 CFR 510.450 and appendix C (Center for Veterinary Medicine, FDA, June 1988) made available with the proposed rule of September 15, 1988). The removal of § 510.450 will not prohibit the continued marketing of those products. Moreover, for four of the six uses for which there are no approved NADA's for sulfonamide-containing drug products, there are approved NADA's for nonsulfonamide drug products (lasalocid, penicillin-streptomycin, and oxytetracycline for use against various diseases in sheep). (Id. at pp. 14 to 22 and appendix C at pp. 6 and 18.)

There are only two uses of a sulfonamide-containing drug product covered by § 510.450, sulfaquinoxaline for use in the control of fowl cholera in pheasants and quail, for which there is no new animal drug with an approved NADA. However, there is a licensed vaccine for the prevention of acute fowl cholera in pheasants and quail. (Id., appendix C at p. 24.) The vaccine is not always effective, but when outbreaks occur, there are straightforward management procedures that limit the spread and recurrence of the disease. (Id. at p. 24.) Moreover, sulfaquinoxaline is not used extensively to treat fowl cholera in those species, and the termination of interim marketing is not expected to produce adverse economic or other harmful effects. (See paragraphs 11, 12, 13, and 15 of this preamble.)

The availability of substitute products aside, FDA emphasizes that, with exceptions not relevant here, sections 301, 501, and 512 of the act (21 U.S.C. 331, 351, and 360b) prohibit the introduction or delivery for introduction into interstate commerce of any new animal drug for which an approved NADA is not in effect. In light of the history of § 510.450 (see 53 FR 35833 and 35834), interim marketing of sulfonamide-containing drug products is no longer consistent with the law or justified by the facts. Absent the requisite showing of effectiveness and safety, including human food safety, in approved NADA's, claims that such products are beneficial and should therefore be allowed to remain on the market necessarily fall short of the mark. (See 53 FR 35833 at 35835.)

2. One comment noted that in the July 5, 1984, notice, FDA stated that the agency intended to publish a notice of opportunity for a hearing (NOOH) on denial of approval fo pending NADA's for sulfonamide-containing drugs for use in food-producing animals that are covered by § 510.450 at the same time the agency published a proposed rule to remove the regulation. The comment then argued that, having published the proposal before the NOOH, the agency should publish the NOOH forthwith.

FDA points out that the NOOH was published soon after the proposed rule. The comment period on the proposal closed on November 14, 1988 (53 FR 35833 at 35836). FDA's Center for Veterinary Medicine (CVM) published the NOOH on November 15, 1988 (53 FR 46050) (corrected 53 FR 49968, December 12, 1988; 53 FR 51950, December 23, 1988; 54 FR 5303, February 2, 1989).

3. One comment supported the proposed rule but urged CVM to carefully examine the need to maintain the availability of sulfathiazole and sulfapyridine. The comment also urged FDA to encourage manufacturers to seek NADA approval for alternative sulfonamide products. Another comment, opposed to the removal of § 510.450 in the near future, urged FDA to take appropriate steps to encourage drug sponsors to meet the requirements for NADA approval for sulfonamide-combination products as well as for sulfathiazole-containing products. According to this comment, one result of the removal of § 510.450 will be the elimination of sulfathiazole, which causes almost no food residue problems, in favor of sulfamethazine, which has been the source of violative residues in pork tissue for the past two decades.

As explained in paragraphs 1 and 5 of this preamble, FDA has concluded that interim marketing of sulfonamide-containing products, including sulfapyridine, sulfathiazole-containing products, and sulfonamide-combination products, is no longer consistent with the law or justified by the facts. The agency advises, however, that there are approved NADA's for sulfonamide- and nonsulfonamide-containing drug products for all the uses of the sulfonamides referred to in the comments (see paragraph 1 of this preamble), and that the removal of § 510.450 will not prohibit the continued marketing of those products. Although there are no approved NADA's for sulfathiazole dosage form drugs, there is an approved application for chlortetracycline, procaine penicillin, and sulfathiazole for various feed uses in swine. (See 21 CFR 558.155.) Thus, the removal of § 510.450 will not result in the elimination of sulfathiazole in favor of sulfamethazine. Additionally, FDA has been and is working with sponsors of NADA's for sulfathiazole-containing products and sulfonamide combination products to help them obtain the data necessary for NADA approval, as urged by the comments. Sponsors of NADA's for sulfapyridine have not been active in seeking approval of the applications.

4. One comment claimed that patents for all the sulfonamide-drugs covered by § 510.450 have expired, as a result of which sponsors that undertook the expense necessary to obtain approval of NADA's would be immediately deluged with competition from generic products that were shown to be bioequivalent to the pioneers. The comment argued that before removing § 510.450, FDA should promulgate regulations that would provide a period of protection for sponsors whose drug products meet the requirements for NADA approval. The comment also argued that the agency must provide a pathway for approval of dosage form therapeutic combination drug products similar to that provided for feed use production drugs before

sponsors of sulfonamide combination products can be expected to obtain NADA approval of such combinations.

Whether the patent and other laws adequately protect the sponsors referred to in the comment is for the Congress to decide; FDA's authority to provide such protection, by regulation or otherwise, is dependent upon legislation. Whether such sponsors are entitled to any period of exclusivity under title I of the Generic Animal Drug and Patent Term Restoration Act, Pub. L. 100–670, 102 Stat. 3971–3984, for products with approved NADA's has not yet been decided by the agency. As FDA advised in the July 5, 1984, notice (49 FR 27546), NADA's for combination sulfonamide-containing drug products that do not contain any other active ingredients will comply with the requirements set out in 21 CFR 514.1(b)(8)(v) for combination drug products without submission of data from studies that compare the combination of sulfonamides with the individual sulfonamides (because all sulfonamides have the same mechanism of action, each individual sulfonamide can be expected to contribute to the total effect of the combination drug product (49 FR 27546)). A combination dosage form drug product containing a sulfonamide and another ingredient, like combination feed use, production drug products, must satisfy those requirements.

5. Several comments, claiming that a good deal of research on various sulfonamide-containing products has been or is about to be undertaken to support NADA approvals, argued that it is unfair, unnecessary, and inappropriate for FDA to remove § 510.450 before the agency has reviewed ongoing research and other data from sponsors, in light of the fact the agency has permitted interim marketing of sulfonamide-containing drugs for many years. The comments suggested that FDA allow sponsors of interim-marketed sulfonamide-containing products time to finish or conduct research for which commitments have been made and submit complete NADA's for their products. The comments suggested that the agency withdraw the proposed rule, not rush to publish a final rule, or at a minimum establish an extended time period between publication of a final rule and its effective date. Additionally, one comment suggested that, rather than remove § 510.450 in its entirety, FDA could terminate interim marketing privileges for sulfonamide-containing products which are not now being marketed or for which no data have as yet been submitted or are being developed, establish criteria and timetable objectives for the remaining products and, on a continuing basis, revoke interim marketing privileges for products which do not meet those objectives. This comment also stated that in implementing such a program, FDA could exercise its discretion and revoke only those "interim approvals" for which there is a clear cut failure to proceed with an adequate program after methods and criteria have been established.

FDA disagrees with these comments. FDA first provided for interim marketing of sulfonamide-containing products under § 135.102 (redesignated as § 510.450) on October 23, 1970; 35 FR 16538. The removal of § 510.450 will become effective on November 7, 1990. (See paragraph 7 of this preamble.) Simply put, the agency has concluded that nearly 19 years of interim marketing are enough. To be sure, it took some time for FDA to complete the process of explaining to all sponsors, in a single document, the requirements for complete NADA's and the methodology to be followed in the requisite studies. But the act places on sponsors, not the agency, the burden of proving in NADA's the effectiveness and safety, including human food safety, of their products before marketing may begin. Furthermore, on May 23, 1986 (see 53 FR 46050), July 5, 1984 (49 FR 27543), and in the 1970's (see 53 FR 46056 to 46058), Refs. 1 through 142), FDA advised individual sponsors of pending NADA's for sulfonamide-containing drug products marketed under § 510.450 of the data, revised labeling, and other information necessary for NADA approval. The agency can no longer affirmatively permit the marketing of products where, as here, studies that should have been finished many years ago are merely said to be underway, about to begin, or the subject of commitments, and the sponsors in question have not yet submitted complete NADA's, let alone obtained approval of the applications. Additionally, with one exception (see paragraph 1 of this preamble), there are approved NADA's—held by other sponsors—for sulfonamide-containing and other drug products for all the uses for which sulfonamide-containing drugs have been marketed under § 510.450.

Even if FDA could affirmatively permit the continued marketing of products under the circumstances, it would not choose to do so. The agency has been unsuccessful in persuading sponsors of the NADA's covering interim marketing of sulfonamide-containing products of the need to complete the applications, and there is no reason to believe that delaying the removal of § 510.450 would prompt the submission of approvable NADA's. (Indeed, of the 142 pending NADA's covering interim marketing of sulfonamide-containing products under § 510.450 as of September 15, 1988, when FDA proposed to remove the regulation, 98 have been the subject of final orders refusing approval, either because the sponsors did not request a hearing in response to the NOOH (see 54 FR 10725; March 15, 1989) or because the sponsors did not submit any data, information, or analysis in support of their hearing requests (see 54 FR 22015; May 22, 1989)). Moreover, FDA could not pick and choose among pending NADA's on the basis of whether data are "being developed." Finally, establishing, monitoring, and enforcing still more criteria and timetable objectives (FDA set out criteria in July 1984 and again in May 1986 (see 53 FR 35833 and 35834)) would inevitably cause unjustifiable delays in terminating interim marketing under whatever remained of § 510.450.

Although the agency is removing § 510.450 in its entirety, FDA is reaffirming (see 53 FR 35834) that two provisions of the regulation continue to represent the agency's interpretation of the act, even though FDA is not retaining the provisions in the Code of Federal Regulations. Those provisions are as follows:

1. The presence of sulfonamide residues in food constitutes an adulteration within the meaning of section 402(a)(2)(D) of the act (21 U.S.C. 342(a)(2)(D)) in the absence of a tolerance for such residues established pursuant to section 512(i) of the act.

2. Sulfonamide-containing drugs for oral, injectable, intrauterine, or intramammary use in food-producing animals are new animal drugs for which approved new animal drug applications are required.

FDA is also reaffirming (see 49 FR 27544 and 27545 and § 510.450(a) (3) and (5) and (c) and (d)) that residue depletion data for each species, which are necessary to permit the assignment of preslaughter withdrawal periods that will ensure that edible products are free of above-tolerance residues, must be submitted for each NADA, and that those data must be collected by using a regulatory method reliable at least to the tolerance for residues of the drug in question.

None of the comments addressed either of the provisions of § 510.450 set out above, and none of the comments argued that residue depletion data are not required to show human food safety. The first provision simply reflects the language of section 402(a)(2)(D) of the

act and FDA's determination, made in the 1970's (see 38 FR 19404; July 20, 1973, and 39 FR 36633; July 22, 1974) and stated in the second provision, that sulfonamide-containing drugs for oral, injectable, intrauterine, or intramammary use in food-producing animals are new animal drugs for which approved NADA's are required. Although sulfonamide-containing drug products have been widely used for an extended period, neither that fact nor anecdotal evidence of safety and effectiveness precludes a finding of new animal drug status. See, e.g., *United States* v. *An Article of Drug * * * Neo-Terramycin*, 540 F. Supp. 363, 369–70 (N.D. Tex. 1982) *aff'd sub nom.*; *United States* v. *An Article of Drug Consisting of 4,680 Pails*, 725 F.2d 976, 987–88 n.26 (5th Cir. 1984); *United States* v. *Articles of Food and Drug * * * Coli-Trol 80*, 372 F. Supp. 915, 918–19 (N.D. Ga. 1974), *aff'd* 518 F.2d 743 (5th Cir. 1975); *United States* v. *Articles of Drug * * * Hormonin*, 498 F. Supp. 424, 432 (D.N.J. 1980), *aff'd without opinion*, 672 F.2d 904 (3d Cir. 1981). Rather, a new animal drug is any animal drug product, regardless of how old, about which insufficient published adequate and well-controlled clinical investigations exist upon which qualified experts can reach a consensus ("general recognition") that the product is safe (including human food safety) and effective. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.* 412 U.S. 609, 629–30 (1973); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).

In order for an animal drug product to be generally recognized, there must be a consensus of expert opinion that the product is safe and effective for its labeled indications, that expert consensus must be based on adequate and well-controlled clinical investigations conducted on the product, and the investigations conducted on the product must be published in the scientific literature and available to experts generally. See, e.g., *United States* v. *Undetermined Quantities * * * Equidantin Nitrofurantoin Suspension*, 675 F.2d 994 (8th Cir. 1982), *cert. denied sub nom. Performance Products, Inc.* v. *United States*, 460 U.S. 1051 (1983) and cases cited there; *United States* v. *Seven Cardboard Cases * * * "100 Capsules NDC * * * Esgic * * * with Codeine Capsules, etc." and Forest Phamaceuticals, Inc.*, 716 F. Supp. 1221 (E.D. Mo. July 10, 1989) and cases cited there), appeal docketed, No. 89–2539EM (8th Cir. September 8, 1989).

An animal drug product that fails to meet any one of the three conditions is "new." (Ibid.) There are no published adequate and well-controlled investigations of any sulfonamide-containing drug product showing that the product is safe and effective for its labeled indications. Accordingly, sulfonamide-containing drugs for oral, injectable, intrauterine, or intramammary use in food-producing animals remain new animal drugs for which approved NADA's are required. (See ibid.) And, as noted above, residue depletion data for each species, collected using a regulatory method reliable at least to the tolerance for residues of the drug in question, must be submitted for each NADA to establish the human food safety of the product.

6. One comment argued that the "withdrawal of interim approval" for sulfonamide-containing products marketed under § 510.450 for which there are comparable competitive products with approved NADA's would raise significant questions of fairness under the principles allegedly established by an unpublished order in *Ivy-Reed Co., Inc.* v. *FDA*, Civil No. 78–2658 (D.N.J. 1978). This comment went on to argue that FDA should proceed uniformly against both "NADA approved and interim approved products simultaneously."

FDA disagrees. In the cited case, the agency had not approved an application for a generic product because of a safety concern but had not initiated proceedings to withdraw approval of the pioneer products, to which the same safety concern applied. Ivy-Reed brought suit against the agency, seeking an order directing FDA to approve the application. The court refused to issue the order sought by Ivy-Reed and ordered the agency to issue the notice required by section 512(c) of the act, either approving the application or giving Ivy-Reed notice of opportunity for a hearing (see 44 FR 1462 and 1463; January 5, 1979). Assuming for the sake of argument that *Ivy-Reed Co., Inc.* v. *FDA* was correctly decided, it is inapplicable here, where FDA is not refusing approval at all. Rather, it is discontinuing the interim marketing privileges it provided in § 510.450 for products that never had approved NADA's. And, the agency's scientific, policy, and legal reasons for removing § 510.450 are wholly irrelevant to the status of the "comparable competitive products with approved NADA's" referred to by the comment. The NADA's for those products met and continue to meet the requirements of the act and FDA's regulations. The sulfonamide-containing products marketed under § 510.450 do not have approved NADA's; whether they should ultimately be refused approval, as CVM has proposed (53 FR 46050), is a question to be resolved in the context of the NOOH and subsequent proceedings.

7. One comment argued that the long marketing history of sulfonamide-containing products governed by § 510.450, as well as the existence of "interim approvals," require that the regulation not be removed until after the sponsors are provided an NOOH and action is taken on the pending NADA's for the existing "interim approvals." Another comment suggested that FDA refrain from initiating regulatory action against a sponsor if a sponsor requests a hearing in response to the NOOH.

FDA rejects these comments. Section 510.450 provided interim marketing privileges rather than "approvals," interim or otherwise, and the agency has concluded that nearly 19 years of such privileges are enough. (See paragraphs 1 and 5 of this preamble.) Effective November 7, 1990, any sulfonamide-containing drug product on the market intended for use in food-producing animals that is not the subject of an approved NADA will be in violation of the act and subject to regulatory action, unless covered by a statutorily-provided exception to the requirement of an NADA. Such a drug product, in other words, will have the same status as any unapproved new animal drug product; the fact that an NADA is pending, i.e., has not been refused approval, will be irrelevant. It is only because of the extent and long history of use of sulfonamide-containing products covered by § 510.450 and of the need for an orderly transition to the use of approved new animal drugs that FDA has decided to make the removal of the regulation effective 90 days after the date of publication of this final rule in the **Federal Register**.

The NOOH was published on November 15, 1988 (53 FR 46050), and CVM is analyzing the data, information, and analyses submitted by sponsors in support of their requests for a hearing. Delaying the removal of § 510.450 until after action is taken on the pending NADA's would merely serve to extend privileges that FDA has concluded are no longer consistent with the law or justified by the facts, as would declining to take regulatory action simply because a sponsor requested a hearing.

8. One comment argued that certain issues surrounding the studies required to obtain approval of NADA's for sulfathiazole, sulfamethazine, and sodium sulfamethazine soluble powder should be considered and resolved

before FDA takes further action on its proposal to revoke § 510.450.

FDA disagrees. CVM reviews of NADA's for these new animal drugs, rather than this or any other rulemaking proceeding, are the proper forums in which to resolve such questions. For example, whether a cross-over bioavailability study of sulfathiazole is unnecessary under certain circumstances, as the comment maintains, is a scientific issue that cannot be resolved without the results of the sponsor's tissue residue study and detailed information about the formulation of the sponsor's sulfathiazole product.

9. One comment claimed that, until the July 5, 1984, notice, FDA did not advise sponsors of NADA's for sulfonamide-containing products marketed under § 510.450 of the requirements for complete NADA's and the methodology to be followed in the requisite studies. The comment argued that, under the circumstances, § 510.450 should not be withdrawn insofar as it applies to sponsors that have been and are now attempting to comply with the agency's requirements. Another comment claimed that the agency has never been forthcoming to these sponsors in advising them of acceptable tolerances. This comment argued that, under the circumstances, removal of the regulation would be inappropriate, unfair, arbitrary and capricious, premature, and unlawful.

FDA rejects these arguments, for the reasons stated in paragraphs 1 and 5 of this preamble. Further, the agency disagrees with the claims on which each of these arguments rests. The July 5, 1984, notice was preceded by extensive written communications concerning the requirements for complete NADA's and the deficiencies in pending applications. (See, e.g., Refs. 1 to 6; see also 53 FR 46056 to 46058, Refs. 1 to 27, 29 to 57, 61 to 86, 88, 90 to 142.) Also, tolerances that would be acceptable to the agency were set out in the mid-1970's (see, e.g., Refs. 2, 4, and 5), in a notice published in the **Federal Register** of September 26, 1980 (45 FR 63930), and in the July 5, 1984, notice (49 FR 27543 at 27544). Even if the claims were correct, however, that would not justify the continuation of interim marketing. (See paragraphs 1 and 5 of this preamble.)

10. One comment argued that pending NADA's for sulfonamide-containing drug products covered by § 510.450 constitute a "license" under the Administrative Procedure Act (APA) (5 U.S.C. 551(8)), and, as such, can be withdrawn only after the sponsors of the applications have been given an opportunity to achieve compliance with the act, relying on 5 U.S.C. 558(c).

FDA disagrees with this argument. The pending NADA's do not constitute a "license" under the APA. Even if they did however, the argument would fail. Section 558(c) of the APA provides in relevant parts:

> Except in cases of willfulness or those in which public health, interest, or safety requires otherwise, the withdrawal, suspension, revocation, or annulment of a license is lawful only if, before the institution of Agency proceedings therefor, the licensee has been given—
>
> (1) Notice by the Agency in writing of the facts or conduct which may warrant the action; and
>
> (2) Opportunity to demonstrate or achieve compliance with all lawful requirements.

For the reasons set out in paragraphs 1 and 5 of this preamble, the removal of § 510.450 is a matter in which "public health, interest, [and] safety require otherwise." In any event, there can be no question that FDA has already provided the sponsors the written notice required by section 558(c)(1) (see paragraphs 5 and 9 of this preamble) and the opportunity to demonstrate or achieve compliance required by section 558(c)(2) (see paragraphs 1, 5, and 9 of this preamble).

11. Two comments argued that FDA's analysis of the economic effects of the removal of § 510.450 is misleading, incomplete, and defective because it does not take into account the cost to food producers or consumers of the removal from the market of sulfonamide-containing products marketed under the regulation. A third comment argued that the net result of the removal of the regulation may well be an increase in the cost of sulfonamide-containing products because of lack of competition in the marketplace.

FDA disagrees with these comments. Consumers and the agricultural sector should not be adversely affected by the removal of § 510.450 because substitute products and management practices are available for all the uses of the sulfonamide-containing drug products covered by the regulation. (See paragraph 1 of this preamble.) The cost of the substitute products and management practices is expected to approximate the cost of the sulfonamide-containing drug products covered by the regulation; the increased demand for substitute products anticipated to follow the removal of § 510.450 should provide sufficient competition among these products to counter any potential price increase. In any event, the cost of medications is only a minimal fraction of the overall cost of production for food animals. Thus, the cost of substitute products will not significantly alter either production costs or consumer prices. Also, FDA notes that, effective January 1, 1991, under the Generic Animal Drug and Patent Term Restoration Act, generic copies of pioneer products may be approved for marketing under abbreviated NADA's which do not require target animal safety or effectiveness data.

12. One comment argued that FDA did not sufficiently address the economic impact of the removal of § 510.450, claiming that the economic analysis set out in the preamble to the proposed rule does not meet the requirements of Executive Order 12291 or the Regulatory Flexibility Act, 5 U.S.C. 603(a), 605(b), and 612.

FDA disagrees. The comment ignores the appropriate application of Executive Order 12291, which requires a regulatory impact analysis only if an agency determines that a rule is a "major rule" as defined in section 1(b) of the Order. FDA has determined, according to the authority granted by the Executive Order, that the removal of § 510.450 is not such a rule. The agency examined the economic consequences of the termination of interim marketing at the time of the proposed rule, detailing in the preamble its projections of minimal economic impact. (See 53 FR 35833 at 35835.) The comment failed to provide FDA with information to justify a change in that analysis. Therefore, as provided in section 605(b) of the Regulatory Flexibility Act, the agency certifies that the removal of § 510.450 will not have a significant economic impact on a substantial number of small entities.

13. One comment argued that removal of § 510.450 would result in FDA's violating the Migratory Bird Treaty Act (the MBTA), 16 U.S.C. 703, citing *Alaska Fish & Wildlife Fed'n* v. *Dunkle*, 829 F.2d 933 (9th Cir. 1987), *cert. denied*, 108 S.Ct. 1290 (1988), *reh'g denied* 108 S.Ct. 2028 (1988) and *Defenders of Wildlife* v. *EPA*, 688 F. Supp. 1334 (D. Minn. 1988). This comment implied that an increased risk to MBTA-protected birds is possible in two respects: by increasing the risk of fowl cholera epidemics in carrier species with a resulting transmission of the disease to MBTA-protected birds, and by decreasing the antimicrobial effects of sulfonamide residues excreted into the environment of fowl cholera carriers.

FDA rejects these arguments, for several reasons: First, there is only one sulfonamide-containing drug covered by § 510.450, sulfaquinoxaline for use in the

control of fowl cholera in pheasants and quail, for which there is no new animal drug with an approved NADA (see paragraph 1 of this preamble); with respect to every other sulfonamide-containing drug, the removal of the regulation could not conceivably violate the MBTA because substitute sulfonamide and nonsulfonamide drug products with approved NADA's are available. (See id.) Second, sulfaquinoxaline is rarely used and, if used, does not eliminate fowl cholera from a population of birds. Rather, the drug reduces the effects of the disease and may create carriers of it. Third, sulfaquinoxaline does not prevent outbreaks of fowl cholera. The drug is used to control the severity of the disease after it has occurred or on premises where the disease organism is recurring. (See finding of no significant impact and environmental assessment at pp. 23 and 24.) Fourth, poultry management procedures effective in preventing fowl cholera are available to producers. (Id. at p. 24.) Fifth, the argument that in the absence of sulfaquinoxaline, fowl cholera will strike not only pheasants and quail but also MBTA-protected birds, is wholly speculative. Indeed, the comment was not supported by any data or other information. Fowl cholera is already present in wild bird populations, including MBTA-protected birds, where drug treatment is rarely if ever provided. One could as easily speculate that the incidence of fowl cholera in wild populations could be increased, rather than decreased, by the possible release of sulfaquinoxaline-treated carriers of the disease.

Neither of the cited cases mandates further action by the agency under the MBTA. In *Alaska Fish & Wildlife Fed'n* v. *Dunkle*, a Federal agency promulgated regulations that permitted hunting of migratory birds protected under the MBTA, in contravention of that statute. In *Defenders of Wildlife* v. *EPA*, birds protected by the MBTA were poisoned by strychnine, which was approved by the Environmental Protection Agency for use as a rodenticide. The court held that the agency was liable for a "taking" of MBTA-protected birds, as the birds had access to the strychnine and died after ingesting it. By contrast, pheasants and quail are not protected under the MBTA (see 50 CFR 10.1 *et seq.*) and, as noted above, the comment did not provide any evidence to indicate, let alone show, that with the unavailability of sulfaquinoxaline for the control of fowl cholera in pheasants and quail, the disease will become more prevalent among birds that are protected under the MBTA.

In preparing the environmental assessment, FDA projected maximum potential losses to the pheasant and quail populations following an outbreak of fowl cholera in compiling a "worst case scenario." Those losses were 6 million pheasants a year and 800,000 quail a year, assuming the absence of sulfaquinoxaline to control the disease. By definition, the "worst case scenario" is not an actual estimate of predicted losses in the pheasant and quail populations, and for the reasons set out in this paragraph, that scenario is anything but likely to occur. More to the point, even if the projected maximum potential losses were actual and accurate estimates, the harm would occur to birds that are not protected under the MBTA, not to birds that are protected under that statute, and the comment failed to establish any link between harm to pheasants and quail, on the one hand, and harm to MBTA-protected birds, on the other.

In FDA's view, if there is a market for new animal drugs to control fowl cholera in pheasants and quail, an NADA will be developed for a drug product with those indications. (See finding of no significant impact and environmental assessment at pp. 26 and 27.) Indeed, the literature reveals that several drugs, including a number of sulfonamides, are being suggested as effective in controlling the disease in both pheasants and quail. (Id. at p. 27.)

14. One comment argued that FDA is obligated to consult with the Fish and Wildlife Service of the Department of Interior before removing § 510.450, to comply with the Endangered Species Act, 16 U.S.C. 1536(a)(1)(2), 1538(a)(1)(b), citing *TVA* v. *Hill*, 437 U.S. 153 (1978) and *Sierra Club* v. *Marsh*, 816 F.2d 1376 (9th Cir. 1987). The comment claimed that, in the absence of sulfaquinoxaline, Endangered Species Act-protected birds will be endangered either directly or through transmission of fowl cholera by pheasant and quail carriers. The comment then argued that this possibility mandates FDA consultation with the Fish and Wildlife Service before removing § 510.450.

FDA disagrees. The cited cases merely hold that a Federal agency is subject to the Endangered Species Act, which does not require additional action by the agency here. FDA has incorporated all Endangered Species Act requirements in 21 CFR 25.5(c)(10) and the Health and Human Services General Administration Manual, part 30, and these requirements have been satisfied. FDA will consult with the Fish and Wildlife Service on any FDA proposal that may affect a species listed in 50 CFR 17.11. No pheasants or quail with ranges in the United States are listed there, and there is no evidence that any of the species listed in 50 CFR 17.11 will be affected by the removal of § 510.450. Pheasants and quail with ranges outside of the United States, although listed in 50 CFR 17.11, are not affected by § 510.450 as it now exists, nor will they be affected upon the effective date of its removal.

15. One comment contended that FDA did not adhere to regulations promulgated by the Council on Environmental Quality at 40 CFR 1500 to 1508 and the requirements of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332 *et seq.* in compiling the environmental assessment and the finding of no significant impact. The comment also contended that the finding of no significant impact is incorrect and that the agency must prepare an environmental impact statement before removing § 510.450.

FDA disagrees with each of these contentions. The agency has promulgated regulations (21 CFR part 25) to ensure adherence to all Council Environmental Quality and NEPA requirements, and has fully complied with those regulations in this matter. The Environmental Assessment was thoroughly researched and prepared according to the standards set out in 21 CFR 25.22(a)(9) and 25.31b and the Council on Environmental Quality's regulations, which implement the National Environmental Policy Act. It explores possible effects of the removal of § 510.450 upon all current uses of new animal drugs marketed under that section, and finds that new animal drug products with approved NADA's, almost all of them sulfonamide-containing, are available for every one of those uses except sulfaquinoxaline for fowl cholera in pheasants and quail. (See paragraph 1 of this preamble.) The environmental assessment also addresses the environmental consequences of the potential shift in chemical introductions resulting from the use of sulfonamide- and nonsulfonamide-containing drug products with approved NADA's (see finding of no significant impact and environmental assessment at pp. 10 to 22) and the environmental consequences of the unavailability of sulfaquinoxaline for the control of fowl cholera in pheasants and quail. (Id. at pp. 23 to 26.) In addition, the environmental assessment addresses mitigation measures (id. at pp. 27 to 29) and regulatory alternatives and expected environmental consequences (id. at pp.

30 and 31), and includes a comparative analysis of the removal of § 510.450 and the alternatives. (Id. at p. 32.)

The environmental assessment amply supports the finding of no significant impact, which concludes that the alternative sulfonamide-containing drug products, those with approved NADA's, share with the unapproved sulfonamides marketed under § 510.450 a similar low potential to cause environmental impacts, that the alternative nonsulfonamide-containing products, also with approved NADA's, have been found not to cause significant impacts, and that the unavailability of sulfaquinoxaline for the control of fowl cholera in pheasants and quail is not expected to produce adverse effects. For all these reasons, an environmental impact statement was not and is not required.

In sum, FDA believes that it has fully complied with the requirements of the Council on Environmental Quality's regulations, with the requirements of 21 CFR part 25, and with the National Environmental Policy Act. FDA reached an "adequately reasoned and explained decision" not to prepare an environmental impact statement. [*National Audubon Soc.* v. *Hester*, 801 F.2d 405, 407 (D.C. Cir. 1986).] Nothing more is required.

16. One comment alleged that FDA did not sufficiently address alternatives to the removal of § 510.450, and argued that a further exploration of alternatives warrants an environmental impact statement. According to the comment, the agency should have considered a "prolonged phaseout period" for the regulation.

FDA disagrees. In the environmental assessment, the agency considered two alternatives: the removal of § 510.450 and no action at all; and FDA concluded, consistent with 21 CFR 25.41(a), that there was no need to examine other regulatory alternatives because no adverse environmental impacts were found for the proposal to remove the regulation. (See finding of no significant impact and environmental assessment at pp. 30 and 31.) Under the circumstances, a prolonged phaseout of § 510.450, like other suggestions in favor of deferring final agency action in this matter (see paragraphs 4 to 7 of this preamble), would be neither consistent with the law nor jusitified by the facts, for the reasons explained in paragraphs 1, 5, 6, and 7 of this preamble.

17. One comment argued that the environmental assessment failed to address the following uncertainties in its analysis: the effect and likely use of substitutes for sulfonamide-containing drugs marketed under § 510.450, the environmental effects of using nonsulfonamide substitute products, and the effect of the removal of § 510.450 on pheasants and quail (including substitute products and disposal concerns), citing *Sierra Club* v. *Marsh*, 769 F.2d 868 (1st Cir. 1985).

FDA rejects the comment. First, each of the uncertainties in question is addressed in the Environmental Assessment. (See finding of no significant impact and environmental assessment at pp. 10 to 31.) Second, the cited case is inapposite. In *Sierra Club* v. *Marsh*, several Federal agencies failed to adequately consider the fact that construction of a cargo port and causeway would lead to further industrial development, and that further development would significantly affect the environment. Here, there has been no such failure. Indeed, the environmental assessment analyzed potential environmental impacts assuming a "worst case scenario" and found that the removal of § 510.450 is not expected to have a significant impact on the human environment.

II. References

The following references, together with the documents cited in the preamble, have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter dated November 5, 1975, from Adriano R. Gabuten, CVM, to Robert R. Baron, Salsbury Laboratories.
2. Letter dated January 12, 1976, from Adriano R. Gabuten, CVM, to Gregory P. Bergt, Consultant, I.D. Russell Co. Laboratories.
3. Letter dated February 5, 1976, from Adriano R. Gabuten, CVM, to Robert R. Baron, Salsbury Laboratories.
4. Letter dated February 6, 1976, from Adriano R. Gabuten, CVM, to I.D. Russell, I.D. Russell Co. Laboratories.
5. Letter dated May 3, 1976, from Adriano R. Gabuten, CVM, to Gregory P. Bergt, Consultant, I.D. Russell Co. Laboratories.
6. Letter dated August 27, 1979, from Charles E. Haines, CVM, to Robert R. Baron, Salsbury Laboratories.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.450 [Removed]

2. Section 510.450 Sulfonamide-containing drugs for oral, injectable, intramammary, or intrauterine use in food-producing animals is removed from subpart E.

Dated: April 7, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90–18248 Filed 8–8–90; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. 89–22]

RIN 2125–AC38

Truck Size and Weight; Saddlemount Combinations

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: This document increases the minimum overall length limit from 65 to 75 feet for drive-away saddlemount vehicle transporter combinations, including those that carry a fullmount. The States must allow these combinations to operate on the National Network (NN) designated for large trucks. This document also makes clear that both saddlemount combinations and saddlemount with fullmount vehicle transporter combinations are specialized equipment. The action is being taken in response to a petition from the National Automobile Transporters Association (NATA) and its member companies.

EFFECTIVE DATE: September 10, 1990.

FOR FURTHER INFORMATION CONTACT: Mr. Max Pieper, Office of Motor Carrier Information Management and Analysis, (202–366–4029) or Mr. Charles Medalen, Office of the Chief Counsel (202–366–1354), Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION: A final rule implementing the truck size and

weight provisions of the Surface Transportation Assistance Act of 1982 (STAA), Public Law 97–424, 96 Stat. 2097, as amended, was published on June 5, 1984 [49 FR 23302] and codified at 23 CFR part 658. Among other things, this rule provided that States could not impose less than a 65 foot overall length limit on saddlemount and fullmount vehicle transporters. The preamble noted that the final rule did not specify how many vehicles must be allowed to be carried in saddlemount and fullmount operations. Also expressed FHWA's intent to initiate further rulemaking on automobile transporters.

This was accomplished through an advance notice of proposed rulemaking (ANPRM) published on October 2, 1984 [49 FR 38958] and a notice of proposed rulemaking (NPRM) published on November 25, 1985 [50 FR 48431]. A final rule published on January 29, 1988 [53 FR 2593], amended 23 CFR 658.13(d)(iii) to read as follows:

> Drive-away saddlemount with fullmount vehicle transporter combinations are considered to be specialized equipment. No State shall impose an overall length limit of less than 65 feet on saddlemount with fullmount combination. (Triple saddlemount combinations shall be allowed when conforming to the 65-foot length limit and the applicable safety regulations at 49 CFR 393.71.)

On September 7, 1988, the National Automobile Transporters Association (NATA) and its member companies petitioned the FHWA to increase the minimum overall length limit of saddlemount and saddlemount with fullmount combinations from 65 to 75. To support its petition, NATA provided with results of two vehicle performance tests conducted by the Western Highway Institute (WHI) and three computer simulations by its contractor, the University Michigan Transportation Research Institute (UMTRI). WHI's tests involved offtracking and stopping distances for a 60-foot double saddlemount and 65, 70, and 75-foot triple saddlemount combinations. UMTRI simulated the braking efficiency, rollover threshold, and rearward amplification of several saddlemount combinations, compared to other combination vehicles now in general use.

After examining the data from these tests, and FHWA published an NPRM on September 8, 1989 [54 FR 37344], proposing to increase the minimum overall length limit of such combinations from 65 to 75 feet and to clarify an ambiguity in the current rule by stating explicitly that both saddlemount and saddlemount with fullmount combinations are specialized equipment.

WHI/UMTRI Saddlemount Tests

Offtracking is the tendency of the rear wheels of a combination vehicle to track inside the path of the front wheels in a low speed turn and outside that path in a highspeed turn. In WHI's field tests, offtracking for the 75-foot triple saddlemount combination, while not as good as for the shorter saddlemount combinations, was better than for the twin 28-foot trailer combination and substantially better than for the 48-foot semitrailer combination. For example, on a 165-foot radius turn, the swept widths for the 75-foot triple saddlemount combination and 60-foot double saddlemount combination were 10.9 and 9.9 feet, respectively. The swept width for the twin 28-foot trailer and 48-foot semitrailer combinations were 12.3 and 14.6 feet, respectively.

The WHI braking test measured the distance from the point where vehicle brakes were applied to the point where it stopped while staying within a 12-foot wide lane. Although the 75-foot triple saddlemount combination did not brake as well as the 60-foot double saddlemount combination at some speeds (232 feet versus 213 feet at 55 mph, for example), its stopping distances at all speeds were well within the limits of Federal Motor Vehicle Safety Standard 121 (49 CFR part 571) (232 feet versus the FMVSS 121 requirement of 246 feet at 55 mph, for example).

The overall length of the vehicles simulated by UMTRI could not be determined with certainty because only distances between axles or between saddlemounts and axles were given. Therefore, they are identified by 73/75 (or 63/65) as being within the range of 73 to 75 (or 63 to 65) feet.

UMTRI's simulations involved four hypothetical saddlemount combinations, three triples and one double. The dimensional variables were the wheelbase of the tractor and the effective wheelbases, sprung weights, and vetical and longitudinal centers of gravity of the towed vehicles. Each axle, except the steering axle of the tractor, was assigned the same total brake force.

A computer program was used to calculate the deceleration each saddlemount combination could achieve before wheel lockup and loss of control occurred, compared to the theoretical maximum deceleration based on tire-road friction. The result was expressed in a percentage, with 100 percent being perfect braking efficiency.

In light braking (deceleration level of 0.1 g's [1]) UMTRI's computer simulation showed that the braking efficiency of the 73/75-foot triple saddlemount combination was similar to the 60-foot double saddlemount combination, the 63/65-foot triple saddlemount combination and the empty 48-foot semitrailer (60 percent versus 66, 61, and 62 percent, respectively). However, they were all substantially less than for the loaded 48-foot semitrailer (96 percent). This is to be expected since the brakes on heavy vehicles are generally better balanced for heavy than for light loads. Similar results were obtained during heavy (0.4 g's) braking (51 percent versus 58, 52, and 59 percent, respectively).

Rollover threshold is the amount of lateral acceleration, in g's, that a turning vehicle will tolerate before rolling over. UMTRI's rollover threshold simulations for the 73/75-foot triple saddlemount combination, 60-foot double saddlemount combination and 63/65-foot triple saddlemount combination produced very similar results (0.542, 0.547, and 0.543 g's, respectively). All were substantially better than for a loaded semitrailer combination (0.24–0.40 g's) but not as good as for an empty semitrailer combination (.70 g's).

Rearward amplification is an expression of the difference in response of the rearmost unit to the towing unit in a tight turn. A ratio of 1.0 indicates that the response of the last trailing unit is the same as for the towing vehicle, while higher values indicate that some exaggeration in the rear trailing unit response is occurring (the "crack-the-whip" effect). In the UMTRI simulation, the 73/75-foot triple saddlemount combination did not perform as well as the 60-foot double saddlemount combination (1.95 vs. 1.53) but did better than the 63/65-foot triple saddlemount combination and the 28-foot twin trailer combination (1.95 versus 2.13 and 2.55, respectively).

Thirteen responses to the NPRM were submitted to the FHWA Docket No. 89–22. The respondents represented State agencies (3), truck manufacturers (4), trade associations (3), carriers (2), and a research institute. Of these, all but two State agencies favored a 75-foot minimum overall length limit for saddlemount combinations.

Discussion

NATA's petition to increase the saddlemount combination length limit by 10 feet was based on two

[1] A "g" is equal to the acceleration of a body cause by the force of gravity.

developments: (1) truck tractors have become longer since the STAA prohibited regulations of their length in 1983, and (2) fuel efficient aerodynamic features are making cabs higher. This often means that saddlemount combinations must be lengthened to stay within State height limits, which in turn may require the elimination of one unit to meet the 65-foot length limit.

In the NPRM, the FHWA solicited comments on the following five matters:

1. The methods and vehicle combinations used and the results obtained in the Western Highway Institute (WHI) and University of Michigan Transportation Research Institute (UMTRI) tests and simulations and other studies regarding the following vehicle characteristics:

a. Offtracking,
b. Braking (stopping distance),
c. Braking efficiency,
d. Rollover, and
e. Rearward amplification.

2. Any other information regarding the performance of saddlemount combinations.

3. The productivity of saddlemount combinations and the need to extend the overall Federal length limits on saddlemount combinations from 65 to 75 feet.

4. The extent to which increasing by regulation the overall length limit of saddlemount combinations from 65 to 75 feet affects, alters or impacts upon State authority to regulate vehicles operating on State highways.

5. Any other information regarding safety concerns related to extending the overall length from 65 to 75 feet.

Comments Submitted to the Docket

1. Research methods and vehicle characteristics.

Seven respondents commented on the methods used and results reported by WHI and UMTRI.

WHI indicated that it and UMTRI stood behind the testing and analytical methods used and the results published in their saddlemount combination test report. NATA reaffirmed the industry's confidence in these tests, as did one of the associations and a carrier. The Motor Vehicle Manufacturers Association and one carrier supported the proposal since it would not only improve productivity but would also provide operating characteristics as good as or better than vehicle combinations presently allowed on the NN.

The Georgia Department of Transportation strongly opposed increasing the minimum overall length limit from 65 to 75 feet. It stated that the information supporting the petition was based solely on computer simulations that was extensions of the computer data used in adopting the 65-foot limit. Georgia argued that actual safety experience with 65-foot combinations is insufficient to evaluate the reliability of the computer models. UMTRI did use computer simulations in preparing certain information on vehicle combinations, but WHI used actual vehicles for its offtracking and stopping distance tests. The State also asserted that the 65-foot limit for triple saddlemount combinations has been in effect for only two years. In fact, such combinations have been authorized since 1984, although the States have been required to allow triple saddlemount combinations at that length for only two years. The driveway carrier accident experience reported by the National Safety Council (NSC), discussed below, shows that saddlemount combinations are safer than some more commonly used combinations. That result is consistent with UMTRI's computer simulations.

2. Any other information regarding the performance of saddlemount combinations.

After a demonstration at the University of Kentucky, the State's Transportation Cabinet concluded that the articulation provided by the saddlemount system is sufficient to provide safe maneuvering for 75-foot saddlemount or saddlemount and fullmount combinations. Kentucky, therefore, expressed no objection to the proposed rule.

3. The productivity of saddlemount combinations and the need to extend Federal minimum length limits from 65 to 75 feet.

Four truck manufacturers, three trade associations, two carriers and one research institute commented on this issue. They emphasized that because the STAA prohibits an overall length limit on the NN, truck tractors are becoming longer and, to be more fuel efficient, are being built with features that improve aerodynamics but increase vehicle height. The NATA estimated that cost savings from $6 to $7 million per year would result from the proposed length limit increase. It based these figures on numerous factors including savings on fuel, wages, operating taxes, travel expenses and the resulting increases in productivity. By dispatching 3 sets of triple saddlemount combinations instead of 4 sets of double saddlemount combinations, productivity would increase 25 percent. The WHI estimated that fuel costs would decrease 30 percent per delivered unit.

4. The extent the proposal alters or impacts upon State authority.

WHI pointed out that the proposal would not preempt State authority in a new area. One association noted that the proposed rule did not clearly indicate that the 75-foot length limit would apply to triple saddlemount and fullmount combinations. The three State agencies which submitted comments on other portions of the rule did not comment on this issue. The purpose of the rule is to apply the 75-foot length limit to all single, double, or triple saddlemount combinations and single, double, or triple saddlemount with fullmount combinations. The final rule has been revised to clearly reflect this intent.

5. Any other information regarding safety concerns related to extending the overall length of saddlemount combinations from 65 feet to 75 feet.

Two truck manufacturers, two associations, and WHI itself argued that WHI's study demonstrated that safety would not be degraded. Furthermore, because fewer combinations would be needed to move the same number of units, total vehicle miles of travel would be reduced, simultaneously reducing exposure and accidents. In addition, two respondents cited National Safety Council (NSC) data that driveaway carriers had a 1987 accident rate of only 4.1 accidents per million miles traveled. This compares with 1987 rates of 8.8 accidents per million miles for all trucks and 5.5 for truckaway automobile transporters. These figures are from the NSC report, "Fleet Accident Rates 1988," which has been included in the public docket on the rule.

Georgia and Kentucky expressed concern that the 75-foot limit may be an intermediate step to longer length limits. The FHWA has a statutory responsibility to promote motor carrier safety. To the extent consistent with that objective, we will also consider the productivity needs of the industry. Petitions for longer vehicle length limits will be approved only when there is clear evidence for their operational safety.

The Vermont Agency of Transportation opposed increasing the overall length of saddlemount combinations off the National Network (NN) due to the State's topography, narrow roads, numerous substandard curves, steep grades, and weather conditions. This is not directly at issue

in this rulemaking. Federal rules on reasonable access, published on June 1 (55 FR 22758), allow States to restrict vehicles on acccess routes they cannot use safely.

Conclusions

After examining the evidence submitted by NATA and the comments to the docket, the FHWA has concluded that extending the length of saddlemount combinations and saddlemount with fullmount combinations from 65 to 75 feet would not make them less safe than other combinations commonly found on the highways. In addition, their accident exposure would be reduced since fewer trips would be required to transport the same number of vehicles and efficiency and productivity would be enhanced. The increased productivity with no overall degradation of highway safety justifies the increase in length from 65 to 75 feet for saddlemount combinations.

The saddlemount definition and length provision in the NPRM have been revised to make clear that both saddlemount combinations and saddlemount with fullmount combinations are specialized equipment. In addition, it was proposed in the NPRM to define "saddlemount" in 23 CFR 658.5(r). However, the term "saddlemount" is already defined in 49 CFR 393.5. In order to remove any possible conflict and to accurately reflect the type of equipment being considered, we have substituted "saddlemount combination" for "saddlemount" in 23 CFR 685.5(r). The definition of "saddlemount combination" is also being corrected to reflect the fact that saddles are sometimes connected to the fifth wheel of a vehicle as well as to the frame.

Regulatory Impact

The FHWA has considered the impact of this rule and has determined that it is not a major rulemaking action within the meaning of Executive Order 12291 and not a significant rulemaking under the regulatory policies and procedures of the DOT. These determinations by the agency are based on the nature of the rulemaking. The FHWA has determined that this rulemaking technically amends the June 5, 1984, final rule [FHWA Docket 83-14, 49 FR 23302], clarifying and further defining certain issues contained therein. The impacts of the provisions addressed in this rulemaking do not differ in substance from those fully considered in the original impact statement accompanying the June 5 final rule. Automobile transporters of all types make up a small segment of the total medium to heavy truck population (approximately 13,000 transporter combinations out of a total medium to heavy truck population of over 2 million.) Although saddlemount combinations constitute an even smaller percentage, productivity gains could be considerable for this minor constituency. Safety considerations have been addressed earlier in this preamble. The Regulatory Impact Analysis prepared for the June 5 rulemaking is available for inspection in the FWHA Public Docket room 4232 in the Headquarters Office, 400 Seventh Street, SW., Washington, DC 20590.

Executive Order 12612 of October 26, 1987, "Federalism," requires that the effect of Federal regulations on the States must be weighed. Any regulatory preemption of State law must be restricted to the minimum level necessary to achieve the objective of the statute under which the regulation is promulgated. In this case, the FHWA previously authorized saddlemount combinations with a 65-foot minimum overall length limit. Therefore, State authority would not be preempted in a new area. The action is also consistent with the intent of the STAA to increase the productivity of the industry without adversely affecting safety.

Under the criteria of the Regulatory Flexibility Act, the FHWA hereby certifies that this action will not have an adverse economic impact on a substantial number of small entities.

A regulatory information number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

List of Subjects in 23 CFR Part 658

Grants programs—transportation, Highways and roads, Motor carrier—size and weight.

Issued on: July 31, 1990.

T.D. Larson,

Administrator.

PART 658—TRUCK SIZE AND WEIGHT: ROUTE DESIGNATION—LENGTH, WIDTH AND WEIGHT LIMITATIONS

In consideration of the foregoing, the FHWA is amending 23 CFR Part 658 as follows:

1. The authority citation for 23 CFR part 658 continues to read as follows:

Authority: Secs. 133, 411, 412, 413, and 416 of Pub. L. 97-424, 96 Stat. 2097 (23 U.S.C. 127; 49 U.S.C. app. 2311, 2312, 2313, and 2316), as amended by Pub. L. 98-17, 97 Stat. 59, and Pub. L. 98-554, 98 Stat. 2829; 23 U.S.C. 315; and 49 CFR 1.48.

2. Section 685.5 is amended by adding paragraphs (s) and (t), as follows:

§ 685.5 Definitions.

* * * * *

(s) *Saddlemount combination.* A saddlemount combination is a combination of vehicles in which a truck or truck tractor tows one or more trucks or truck tractors, each connected by a saddle to the frame or fifth wheel of the vehicle in front of it. The saddle is a mechanism that connects the front axle of the towed vehicle to the frame or fifth wheel of the vehicle in front and functions like a fifth wheel kingpin connection. When two vehicles are towed in this manner the combination is called a double saddlemount combination. When three vehicles are towed in this manner, the combination is called a triple saddlemount combination.

(t) *Fullmount.* A fullmount is a smaller vehicle mounted completely on the frame of either the first or last vehicle in a saddlemount combination.

3. Section 658.13(d)(1)(iii) is revised to read as follows:

§ 658.13 Length.

* * * * *

(d)(1) * * *

(iii) Drive-away saddlemount vehicle transporter combinations and driveaway saddlemount with fullmount vehicle transporter combinations are considered to be specialized equipment. No State shall impose an overall length limit of less than 75 feet on such combinations. This provision applies to saddlemount combinations with up to three saddlemounted vehicles. Such combinations may include one fullmount. Saddlemount combinations must also comply with the applicable safety regulations at 49 CFR 393.71.

* * * * *

[FR Doc. 90-18661 Filed 8-8-90; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-300 Re; Notice No. 694]

RIN 1512-AA07

Realignment of the Eastern Boundary of the Alexander Valley Viticultural Area and the Northeastern Boundary of the Northern Sonoma Viticultural Area (88F-120P)

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

ACTION: Treasury decision; final rule.

SUMMARY: This final rule amends the eastern boundary of the Alexander Valley viticultural area to encompass the planted areas of Gauer Ranch and Chestnut Springs Vineyards. Also, the northeastern boundary of the Northern Sonoma viticultural area is being amended to coincide with the amendment of the boundary for the Alexander Valley viticultural area. The amended boundary conforms, in part, to the boundary proposed by Group B of the original Alexander Valley petitioners. Approximately 19,085 acres of territory are added to the Alexander Valley and Northern Sonoma viticultural areas. Of these, 165 acres are currently planted to grapes, and another 460 acres are scheduled to be planted within the next three to five years.

EFFECTIVE DATE: September 10, 1990.

FOR FURTHER INFORMATION CONTACT: David W. Brokaw, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, Ariel Rios Federal Building, 1200 Pennsylvania Avenue NW., Washington, DC 20226 (202) 566-7626.

SUPPLEMENTARY INFORMATION:

Background

On October 2, 1979, ATF published Treasury Decision ATF-60 (44 FR 56692) which added a new part 9 to 27 CFR, providing for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25a(e)(1), title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographic features, the boundaries of which have been delineated in subpart C of part 9. Section 4.25a(e)(2), title 27, CFR, outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area. The petition should include:

(a) Evidence that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical characteristics (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and

(e) A copy (or copies) of the appropriate U.S.G.S. map(s) with the proposed boundaries prominently marked.

T.D. ATF-187

T.D. ATF-187, which was published in the **Federal Register** on October 24, 1984, established the Alexander Valley viticultural area effective November 23, 1984. Two groups had presented petitions for the establishment of an Alexander Valley viticultural area, and a hearing was held on January 24, 1983, concerning establishment of the viticultural area. In the final rule, ATF found that the general area encompassed within the boundaries proposed by the second group, ("Group B"), merited establishment as the Alexander Valley viticultural area. Therefore, the viticultural area established by the final rule generally corresponded to the area proposed by Group B. However, their proposed boundaries were modified to exclude several mountainous areas encompassed by the eastern and northwestern boundaries, which ATF found possessed viticultural features which were distinguished by geographical features from the rest of the proposed viticultural area. Specifically, ATF found that the mountainous areas to the east were characterized by soils primarily of the Goulding-Toomes-Guenoc association, while the valley floor was characterized by soils of the Yolo-Cortina-Pleasanton association. ATF noted that virtually all grapes in the Alexander Valley area were grown on the valley floor, adjacent river terraces, and the lower slopes rising out of the valley. The U.S.G.S. 7.5 minute topographic maps reviewed by ATF did not depict any vineyards in the mountainous areas. Finally, ATF found no evidence that the name Alexander Valley was locally and/or nationally known as referring to those mountainous areas, or that the historical or current boundaries of Alexander Valley had ever included those areas. Therefore, ATF concluded that the eastern boundaries proposed by Group B encompassed mountain areas which lay outside the actual geographic and viticultural limits of Alexander Valley, and those boundaries were modified accordingly.

Petition

ATF received a petition for amendment of the eastern boundary of Alexander Valley viticultural area to encompass the planted and soon-to-be-planted areas as Gauer Ranch and Chestnut Springs Vineyards. The petition was submitted by Edward H. Gauer of Gauer Ranch and Ellis J. Alden of Chestnut Springs Vineyards.

Mr. Gauer stated that his 6,000-acre ranch includes property on the valley floor and land rising to the northeast into the hills. Mr. Gauer began planting vineyards in Alexander Valley in 1972. Over the next five years he established 251 acres of vineyards on the valley floor and at low elevations in the foothills. Since 1977 an additional 142 acres have been planted on the hillsides, and another 392 acres of potential new vineyard sites have been chosen.

Mr. Alden stated that he purchased his 1,400 acre ranch in the hills east of Geyserville in 1986 and planted his first vineyards in 1988. Thirteen acres of Cabernet grapes are in the ground; a total of 100 acres are planned for the level and nearly level expanses of the upland valley on his ranch.

Mr. Gauer recently learned that a large part of his property was excluded from the official Alexander Valley viticultural area boundaries which were established in 1984. Both of the petitions as originally submitted included all of Mr. Gauer's hillside vineyards, as well as the site which has now been planted to Mr. Alden's vineyards. Evidence at the hearing did not focus on the exclusion of vineyards of higher elevation. Both of the current petitioners were under the erroneous impression that their properties were included in the Alexander Valley viticultural area boundaries. However, the boundaries described in the final rule excluded a portion of Mr. Gauer's vineyards, and totally excluded the property currently owned by Mr. Alden. When T.D. ATF-187 was issued, ATF was unaware that the boundaries would exclude portions of Mr. Gauer's vineyards from the Alexander Valley viticultural area. ATF mistakenly believed that there were no vineyards planted in the mountainous areas to the east of the eastern boundary line. The petition thus requested an amendment of the eastern

boundary of the Alexander Valley viticultural area to include the vineyards owned by the petitioners.

Northern Sonoma

ATF's amendment of the boundary of the Alexander Valley viticultural area affects the boundary of the Northern Sonoma viticultural area.

In the preamble to Notice No. 472 proposing the Northern Sonoma viticultural area, ATF stated its intention to have the proposed boundary coincide generally with the "outer" portions of the boundaries of the proposed Alexander Valley, Dry Creek Valley, Russian River Valley, and Knights Valley viticultural areas. In the preamble to T.D. ATF-204, ATF stated that these four areas all fit perfectly together dividing northern Sonoma County into four large areas with the Northern Sonoma area using all of the outer boundaries of these four areas with the exception of a small area having nearly 300 acres of grapevines and possessing the same geographical features as the rest of the Northern Sonoma area.

Therefore, ATF is amending the northeastern boundary of the Northern Sonoma viticultural area to coincide with the amended eastern boundary for the Alexander Valley viticultural area.

Evidence of Name

The petitioners submitted evidence that the area was known as Alexander Valley at the time the final boundaries were established in 1984, and has been known as part of Alexander Valley since then. Several letters from owners of neighboring vineyards, including one from a member of the Alexander Valley Appellation Committee, stated that the area in question is locally known as part of Alexander Valley. The letters supported the petitioners' contention that their vineyards had been left out of the Alexander Valley boundaries by mistake. Also, letters from several wineries indicated that they had used grapes from the area in question in wines which were labeled as coming from the Alexander Valley.

Newspaper and magazine articles submitted by the petitioners referred to the Gauer ranch as being located in the Alexander Valley area. In addition, a map created in early 1984, before the final rule (T.D. ATF-187) on Alexander Valley was published, and distributed nationally by the Sonoma County Wineries Association, shows the boundaries of the Alexander Valley viticultural area as encompassing the vineyards owned by the petitioners.

Topography

The elevations found within the petitioned area are consistent with elevations inside the currently defined boundaries of Alexander Valley. Elevations in the northeastern corner of the appellation, which are the highest in the Alexander Valley viticultural area, range from 1,600 to 2,400 feet. In the area within the amended boundary, elevations range from 600 to 2,000 feet. The amended boundary approximates a minor watershed boundary within the larger Russian River watershed. To the southwest of the amended boundary line (i.e., the foothills currently in Alexander Valley viticultural area and the area added to the appellation) surface water drains directly into the Russian River. To the northeast of the line, surface water drains first into Sulphur Creek and its tributaries and from there into the Russian River. This natural boundary proceeds from the top of Black Mountain along a ridge line that bisects Mr. Alden's Ranch.

Climate

The climate of the added area falls within the range of climate found inside the currently approved Alexander Valley appellation. The climate of Alexander Valley contains a certain amount of variation. For example, temperatures increase as one travels from north to south; fog affects only the southern portion of the valley. In general, the climate of Alexander Valley is characterized as a Region III climate according to the system developed by Amerine and Winkler.

No long range temperature studies for either the Gauer Ranch or Chestnut Springs Ranch have been made. However, the petitioners stated, "years of viticultural experience on the Gauer Ranch indicate that the area has a region III climate, suitable for the production and consistent ripening of late varieties such as Cabernet Sauvignon, yet not too warm to produce excellent quality Chardonnay, a relatively early variety."

Soils

A very general soil survey map of Sonoma County put out by the U.S. Department of Agriculture Forest Service and Soil Conservation Service (May 1972), which categorizes soil groupings into ten types, characterizes the primarily alluvial soils of the valley floor as the Yolo-Cortina-Pleasanton Association. Proceeding northeast into the foothills, the map identifies the next soil grouping as the Goulding-Toomes-Guenoc Association. Farther east and running parallel to this association lies another grouping classified as the Yorkville-Suther Association. The rugged mountainous area beyond is mapped as the Los Gatos-Hennecke-Maymen Association. The current eastern boundary of the appellation runs within the area marked Goulding-Toomes-Guenoc, except for the expanded area in the northeast corner, which is mapped as Yorkville-Suther.

However, a closer examination of U.S. Department of Agriculture Forest Service and Soil Conservation (May 1972) large scale soil maps of the eastern half of Alexander Valley suggests that the distinctions between the general soil associations of the foothills are not so clear-cut. The close-in foothills, inside the current Alexander Valley viticultural area boundaries, contain significant quanitites of many of the same soils as the foothills within the amended boundary area.

The eastern foothills officially accepted as part of Alexander Valley show substantial areas of Suther loam, Laughlin loam, Suther-Laughlin loams, Spreckels loam soils, and smaller areas of Sobrante loam, Yorkville clay loam, Pleasantown gravelly loam, Josephine loam, Hennecke gravelly loam, and others including Montara cobbly clay loam, Guenoc gravelly silt loam, Supan silt loam, and Toomes rocky loam. The principal soils in this list are classified as uplands range soils.

The area within the amended boundary shows predominantly Suther loam, Laughlin loam, Suther-Laughlin loams, Yorkville clay loam, and Sobrante loam soils, with smaller areas of Josephine loam, Hennecke gravelly loam, and others. The principal soils, here again, are classified as uplands range soils.

The area outside the amended boundary has large areas of Hennecke gravelly loam, Los Gatos gravelly loam, Stonyford gravelly loam, Josephine loam, Suther-Laughlin loams, Hugo very gravelly loam, and Laughlin loam soils, and smaller areas of Maymen gravelly sandy loam, Hugo-Atwell complex, rock land, and others. The principal soils in this group are mountainous/wilderness type soils.

Thus, in the eastern foothills of Alexander Valley, like in most parts of Sonoma County, there is a great diversity of soil types. There are, however, unifying themes as well. As described above, the same soils reappear throughout the foothills. East of the amended boundary, where the terrain becomes appreciably more rugged, different soil types appear and become predominant.

Notice of Proposed Rulemaking

On December 29, 1989 (54 FR 53653), Notice No. 694 was published in the **Federal Register** with a 45 day comment period. In that notice, ATF requested comments regarding the proposal to amend the eastern boundary of the Alexander Valley viticultural area to encompass the planted areas of Gauer Ranch and Chestnut Springs Vineyards. ATF also proposed the amendment of the northeastern boundary of the Northern Sonoma viticultural area to coincide with the proposed amendment of the boundary for the Alexander Valley viticultural area. During the 45 day comment period, no comments were received.

Miscellaneous

ATF does not wish to give the impression that by approving this realignment of the boundary common to the Alexander Valley and Northern Sonoma viticultural areas that it is approving or endorsing the quality of the wine derived from these two viticultural areas. ATF is approving these viticultural areas as being distinct and not better than other areas. By approving these realignments, wine producers within these areas are allowed to claim a distinction on labels and advertisements as to the origin of the grapes. Any commercial advantage gained can only come from consumer acceptance of wines from "Alexander Valley" and "Northern Sonoma."

Regulatory Flexibility Act

It is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities. 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 final rule 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 effects on competition, employment, investment, productivity, innovation, or on the ability of the 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 David W. Brokaw, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

Authority and Issuance

27 CFR Part 9, American Viticultural Areas, is amended as follows:

PART 9—[AMENDED]

Paragraph 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 9.53 is amended by revising paragraphs (c) (37) through (42), removing paragraphs (c) (43) and (44), and redesignating paragraphs (c) (45) and (46) as (c) (43) and (44) to read as follows:

§ 9.53 Alexander Valley.

* * * * *

(c) *Boundary.* * * *

(37) Then northerly along the western lines of section 4, of T. 9 N, R. 8 W., and sections 33, 28, 21, 16, and 9 of T. 10 N., R. 8 W.;

(38) Then westerly along the northern lines of section 8 and 7, T. 10 N., R. 8 W. and section 12, T. 10 N., R. 9 W. to the southeastern corner of section 2, T. 10 N., R. 9 W.;

(39) Then northwesterly in a straight line to the eastern line of section 3 at 38 degrees 45 minutes latitude, T. 10 N., R. 9 W.;

(40) Then westerly along latitude line 38 degrees 45 minutes to the point lying at 122 degrees 52 minutes 30 seconds longitude;

(41) Then northwesterly in a straight line to the southeast corner of section 4, T. 11 N., R. 10 W., on the Asti, Quadrangle map;

(42) Then northeasterly in a straight line to the southeast corner of section 34, T. 12 N., R. 10 W.;

Par. 3. Section 9.70(b) is revised to read as follows:

* * * * *

§ 9.70 Northern Sonoma.

(b) *Approved maps.* The approved maps for determining the boundary of the Northern Sonoma viticultural area are the U.S.G.S. Topographical Map of Sonoma County, California, scale 1:100,000, dated 1970, the Asti Quadrangle, California, 7.5 minute series (Topographic) Map, dated 1959, photorevised 1978, and the Jimtown Quadrangle, California-Sonoma County, 7.5 Minute series (Topographic) Map, dated 1955, photorevised 1975.

Par. 4. Section 9.70 is amended by revising paragraphs (c) (10) through (26) and by removing paragraphs (c) (27) and (28) to read as follows:

* * * * *

(c) *Boundary.* * * *

(10) The boundary proceeds northerly along the western lines of section 4, of Township 9 North, Range 8 West, and sections 33, 28, 21, 16, and 9 of Township 10 North, Range 8 West of the Jimtown Quadrangle map.

(11) The boundary proceeds westerly along the northern lines of sections 8 and 7, Township 10 North, Range 8 West and section 12, Township 10 North, Range 9 West to the southeastern corner of section 2, Township 10 North, Range 9 West.

(12) The boundary proceeds northwesterly in a straight line to the eastern line of section 3 at 38 degrees 45 minutes latitude, Township 10 North, Range 9 West.

(13) The boundary proceeds westerly along latitude line 38 degrees 45 minutes to the point lying at 122 degrees 52 minutes 30 seconds longitude.

(14) The boundary proceeds northwesterly in a straight line to the southeast corner of section 4, Township 11 North, Range 10 West, on the Asti, Quadrangle map.

(15) The boundary proceeds northeasterly in a straight line to the southeast corner of section 34, Township 12 North, Range 10 West.

(16) The boundary proceeds north along the east boundary of section 34, Township 12 North, Range 10 West on the U.S.G.S. Topographical Map of Sonoma County, California, to the Sonoma County-Mendocino County line.

(17) The boundary proceeds along the Sonoma County-Mendocino County line west then south to the southwest corner of section 34, Township 12 North, Range 11 West.

(18) The boundary proceeds in a straight line east southeasterly to the

southeast corner of section 2, Township 11 North, Range 11 West.

(19) The boundary proceeds in a straight line south southeasterly to the southeast corner of section 24, Township 11 North, Range 11 West.

(20) The boundary proceeds in a straight line southeasterly across sections 30, 31, and 32 in Township 11 North, Range 10 West, to the point at 38 degrees 45 minutes North latitude parallel and 123 degrees 00 minutes East longitude in section 5, Township 10 North, Range 10 West.

(21) The boundary proceeds along this latitude parallel west to the west line of section 5, Township 10 North, Range 11 West.

(22) The boundary proceeds along the section line south to the southeast corner of section 18, Township 9 North, Range 11 West.

(23) The boundary proceeds in a straight line southwesterly approximately 5 miles to the peak of Big Oat Mountain, elevation 1,404 feet.

(24) The boundary proceeds in a straight line southerly approximately 2¾ miles to the peak of Pole Mountain, elevation 2,204 feet.

(25) The boundary proceeds in a straight line southeasterly approximately 4¾ miles to the confluence of Austin Creek and the Russian River.

(26) The boundary proceeds along the Russian River northeasterly, then southeasterly to the beginning point.

Signed: June 22, 1990.

Daniel R. Black,

Acting Director.

Approved: June 20, 1990.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 90-18507 Filed 8-8-90; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 0

[Order No. 1441-90]

INTERPOL—United States National Central Bureau; Establishment of User Fees

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: On August 23, 1989, the Department of Justice, United States National Central Bureau (USNCB)–INTERPOL, published a notice of proposed rulemaking to amend its regulations to establish a system of user fees for the noncriminal inquiries it processes yearly. The system will permit the USNCB to recover the administrative costs the USNCB incurs when processing these noncriminal inquiries. No comments having been received, this final rule is being published without change from the proposed regulations.

EFFECTIVE DATE: August 9, 1990.

FOR FURTHER INFORMATION CONTACT: Ernest M. Buck, Deputy Assistant Chief, Financial Fraud Analysis Section, U.S. National Central Bureau (INTERPOL), (202) 272-8383. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: This regulation will permit the collection of user fees for noncriminal inquiries to the USNCB, such as background checks pertaining to adoptions, gaming licensing, and state bar examination applicants. The fees are intended to recover the administrative costs the USNCB incurs in processing the noncriminal inquiries.

This regulation is not a major rule within the meaning of Executive Order 12291. This regulation will not have an impact on a significant number of small business. 5 U.S.C. 901.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, organization and functions (Government agencies), Whistleblowing.

By the authority vested in me including 28 U.S.C. 509, and 5 U.S.C. 301, subpart F-2 of part 0 of title 28 of the Code of Federal Regulations is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301, 2303, 3103; 8 U.S.C. 1103, 1324A, 1427(g); 15 U.S.C. 644(k); 18 U.S.C. 2254, 3621, 3622, 4001, 4041, 4042, 4044, 4201 *et seq.*, 6003(b); 21 U.S.C. 871, 873(a), 881(d), 904; 22 U.S.C. 263a, 1621-1654o, 1622 note; 28 U.S.C. 509, 510, 515, 516, 519, 524, 543, 552, 552a, 569; 31 U.S.C. 1108, 3801 *et seq.*; 50 U.S.C. App. 1989b, 2001-2017p; Pub. L. 91-513, sec. 501; E.O. 11919; E.O. 11267; E.O. 11300; Pub. L. 101-203.

2. Subpart F-2, § 0.34 is amended by adding a new paragraph (g) to read as follows:

§ 0.34 General functions.

* * * * *

(g) Establish and collect user fees to process name checks and background records for licensing, humanitarian and other non-law enforcement purposes.

Dated: July 31, 1990.

Dick Thornburgh,

Attorney General.

[FR Doc. 90-18572 Filed 8-8-90; 8:45 am]

BILLING CODE 4410-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3814-5]

Approval and Promulgation of State Implementation Plans; North Dakota; Group III PM10 and Other Regulation Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is today approving revisions to North Dakota's State Implementation Plan (SIP) submitted by the Governor on April 18, 1989. This approval is only for those revisions which updated and revised State rules (including PSD regulations) and control strategies to address PM10, and made minor updates to various other regulation revisions, including the revisions to the Control of Pesticides regulation. The April 18, 1989 submittal (1) established new and revised existing New Source Performance Standards (NSPS), (2) revised existing National Emission Standards for Hazardous Air Pollutants (NESHAPs), (3) updated and revised State rules (including PSD regulations) and control strategies to address PM10, (4) made minor updates to various other State regulations, including the revisions to the Control of Pesticides regulation, and (5) added a control strategy to address visibility. The NSPS additions and revisions, and NESHAPs revisions, are being addressed in separate actions. The visibility control strategy was addressed at 54 FR 41094, October 5, 1989. This action updates the North Dakota SIP to incorporate the control strategy for Group III PM10 areas and the revisions to the Air Pollution Control Rules. EPA proposed to approve this action at 54 FR 40133, September 29, 1989 (with corrections at 54 FR 43521, October 25, 1989). No comments were received.

EFFECTIVE DATE: This rule will become effective on September 10, 1990.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection between 8 a.m. and 4 p.m., Monday through Friday at the following offices: