

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the delegations of authority with respect to animal drugs to incorporate provisions for feed mill licensing in accordance with the Animal Drug Availability Act (ADAA) of 1996. The ADAA amended some sections of the Federal Food, Drug, and Cosmetic Act (the act) to require a single facility license for the manufacturer of medicated feeds containing approved new animal drugs, rather than multiple medicated feed applications for each feed mill, as previously required by the act. This notice also updates position and component titles and associated delegations of authority within the Center for Veterinary Medicine (CVM) as a result of organizational restructuring.

EFFECTIVE DATE: December 22, 1998.

FOR FURTHER INFORMATION CONTACT:

Richard L. Arkin, Center for Veterinary Medicine, Food and Drug Administration, 7600 Standish Pl., Rockville, MD 20855, 301-827-0141, or
Loretta W. Davis, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4809.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority in subpart B of part 5 (21 CFR part 5) in order to revise §§ 5.83 and 5.84 to include additional authorities with regard to the approval of the medicated feed mill license applications. The ADAA (Pub. L. 104-250) amended section 512(a) and (m) of the act (21 U.S.C. 360b(a) and (m)). Moreover, this final rule reflects specific organizational, position, and title revisions within CVM due to organizational restructuring of specific components.

Further redelegation of the authorities delegated is not authorized at this time. Authority delegated to a position may be exercised by a person officially designated to serve in such position in

an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; 15 U.S.C. 1451-1461; 21 U.S.C. 41-50, 61-63, 141-149, 321-394, 467f, 679(b), 801-886, 1031-1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u-300u-5, 300aa-1; 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124-131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220-223.

2. Section 5.83 is amended by revising the section heading, paragraphs (c)(1) and (c)(2), and paragraph (d) to read as follows:

§ 5.83 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

* * * * *

(c) * * *

(1) The Director, Division of Human Food Safety, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs pursuant to section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

3. Section 5.84 is amended by revising the section heading and paragraphs (a)(1) and (a)(3) to read as follows:

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) * * *

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted pursuant to section 512(m) of the Federal Food, Drug, and Cosmetic Act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250).

* * * * *

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

* * * * *

Dated: December 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-33830 Filed 12-21-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

RIN 2125-AE47

Truck Size and Weight; Technical Corrections

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule; technical corrections.

SUMMARY: This document amends truck size and weight regulations by changing the definition of automobile transporters to include those transporting towed vehicles and truck camper units and extending the Interstate System axle weight exemption for public transit buses to October 1, 2003, as provided by the Transportation Equity Act for the 21st Century (TEA-21), Pub. L. 105-178, 112 Stat. 107. Five additional technical corrections are also being made, to add Alligator Alley (I-75) to the National Network (NN) listing in Florida; clarify that a State's grandfathered weight limits for divisible vehicles or loads on the Interstate System are permanently vested; clarify that the length of cargo carrying units subject to the freeze in the Intermodal Surface Transportation Efficiency Act of

1991 (ISTEA), Pub. L. 102-240, 105 Stat. 1914, are measured from the front of the first unit to the rear of the last; clarify that the prohibition against an overall length limit on truck tractor-semitrailers or truck tractor-semitrailer-trailer combinations is not affected by grandfathered semitrailer lengths or kingpin settings; and correct the routes available under the ISTEA freeze in Utah for truck-trailer-trailer combinations.

DATES: The effective date for this rule is December 22, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Klimek, Office of Motor Carrier Information Analysis, (202) 366-2212 or Mr. Charles Medalen, Office of the Chief Counsel, (202) 366-1354, Federal Highway Administration, Department of Transportation, 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 Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. DOT Dockets, Room PL-401, by using the universal resource locator (URL): <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may reach the **Federal Register's** home page at: <http://www.nara.gov/fedreg> and the Government Printing Office's database at: <http://www.access.gpo.gov/nara>.

Automobile Transporters

Prior to the signing of TEA-21 on June 9, 1998, the definition of an automobile transporter in 23 CFR 658.5 read as follows:

Any vehicle combination designed and used specifically for the transport of assembled (capable of being driven) highway vehicles.

Section 4005 of TEA-21 amended 49 U.S.C. 31111(a) by adding a new paragraph (1) which defined "automobile transporter" as follows:

(1) **AUTOMOBILE TRANSPORTER.**—The term "automobile transporter" means any vehicle combination designed and used specifically for the transport of assembled highway vehicles, including truck camper units.

The deletion of the parenthetical phrase, "capable of being driven" from the definition indicates that the purpose

was to include vehicles that could not be driven, that is, were not self-propelled. However, they must still be finished vehicles capable of operating on highways, which means, among other things, equipped with wheels. This would include trailers designed to be towed by power units at highway speeds. The one exception to this is a truck camper unit, which the Conference Report on TEA-21 [H.R. Conf. Rep. No. 105-550, at 488 (1998)] explained as follows:

The conference adopts the Senate provision. The conference notes that the phrase "truck camper units" is defined in the ANSI A119.2/NFPA 501C standard on recreational vehicles as "a portable unit constructed to provide temporary living quarters for recreational, travel, or camping use, consisting of a roof, floor, and sides, designed to be loaded onto and unloaded from the bed of a pickup truck" (1996 edition).

This describes a wheel-less unit designed to be loaded on the bed of a pickup truck before it can operate on a highway. Other wheel-less units would have to meet this same definition in order for the transporting unit to be considered an automobile transporter.

Vehicles transporting wrecked automobiles or vehicles used solely to compete in motorsport competition events may not be considered automobile transporters. Wrecked automobiles are those that are either not operable, or if operable to some extent, could not operate safely on the highways. Vehicles used solely to compete in motorsport competition events are those that could not legally operate on the highways. In addition, vehicles transporting incomplete vehicles, such as "glider kits" (which basically consist of a chassis), that require the addition of further components in order to operate on highways may not be considered automobile transporters.

Public Transit Buses

Section 1212(c) in TEA-21 amended Section 1023(h)(1) of the Intermodal Surface Transportation Efficiency Act of 1991 (23 U.S.C. 127 note) by extending the Interstate System axle weight exemption for public transit buses to October 1, 2003. Provisions in 23 CFR 658.17(k) are changed accordingly.

National Network—Florida

The listing for the National Network in Florida in appendix A to 23 CFR 658 contains a "Note" reading as follows:

I-75—Alligator Alley/FL 84 (Toll) between Golden Gate and US 27 Andytown is a designated part of the

Interstate System but is unsigned and not available until constructed to current Interstate standards.

The Florida Division Office of the Federal Highway Administration has verified that Alligator Alley is now complete and has been constructed to Interstate standards. Appendix A is amended accordingly by eliminating the "Note."

Measurement of Cargo-Carrying Length

Section 4006 of the ISTEA amended section 411 of the Surface Transportation Assistance Act of 1982 (STAA) by adding subsection (j)(7) [now codified at 49 U.S.C. 31112(a)(1)], reading as follows:

CARGO CARRYING UNIT DEFINED.—As used in this subsection, "cargo carrying unit" means any portion of a commercial motor vehicle combination (other than the truck tractor) used for the carrying of cargo, including a trailer, semitrailer, or the cargo carrying section of a single unit truck.

This definition was carried forward into 23 CFR 658.5. However, its significance is found in Sec. 411(j)(1) which froze the length of the cargo carrying units of vehicles with two or more such units to not more than what was in actual, lawful operation in a State on June 1, 1991 [now 49 U.S.C. 31112(b)]. The current definition has been interpreted by some to mean that the length of each cargo carrying unit is to be measured separately and added together to get a total length. However, Sec. 411(j)(3) [49 U.S.C. 31112(a)(2)] provided as follows:

MEASUREMENT OF LENGTH.—For purposes of this subsection, the length of the cargo carrying units of a commercial motor vehicle combination is the length measured from the front of the first cargo carrying unit to the rear of the last cargo carrying unit.

In order to clarify how the cargo carrying units are to be measured to determine their allowable length under the ISTEA freeze, the definition of cargo carrying unit in 23 CFR 658.5 is amended by adding a sentence at the end specifying that they are to be measured from the front of the first unit to the rear of the last, including the hitch(es) between the units.

Grandfathered Semitrailer Lengths

Regulations in 23 CFR 658.13(b)(3) read as follows:

Except as noted in paragraphs (c)(1) and (2) of this section, no State shall impose an overall length limitation on commercial vehicles operating in truck tractor-semitrailer or truck tractor-

semitrailer-trailer combinations (emphasis added).

Paragraphs (c) (1) and (2) relate to the requirement that States must allow the use of grandfathered length semitrailers. The underlined provision suggests that there is some exception to the prohibition against an overall length on truck tractor-semi-trailer and truck tractor-semi-trailer-trailer combinations depending on the grandfathered length. It is deleted in order to clarify that the ban on overall length limits has nothing to do with grandfathered semitrailer lengths.

Grandfathered Weight Limits

Some States have asked whether they would lose their maximum grandfathered weight limits on the Interstate System by adopting lower weight limits. No, they would not. Grandfathered weights are vested on the date specified by Congress and are not affected by subsequent State action. In order to clarify this, a sentence is added at the end of 23 CFR 658.17(i) reading as follows:

Grandfathered weight limits are vested on the date specified by Congress and remain available to a State even if it chooses to adopt a lower weight limit for some period of time.

ISTEA Freeze—Utah

The maximum cargo carrying length of commercial motor vehicles under the ISTEA freeze is shown in appendix C to 23 CFR 658. The routes for truck-trailer-trailer combinations in Utah are shown as “Same as the UT-TT2 *combination with a cargo-carrying length greater than 85 feet*” (emphasis added). This fails to provide routing information for truck-trailer-trailer combinations with a cargo-carrying length of less than 85 feet. Information previously filed by the State shows that the routing for truck-trailer-trailer combinations is the same in all cases as for UT-TT2s (truck tractor and 2 trailing units). The text for “Routes” is revised to reflect this.

Rulemaking Analyses and Notices

The Administrative Procedure Act allows agencies engaged in rulemaking to dispense with prior notice to the public when the agency for good reason finds that such procedure is impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b). The FHWA has determined that providing prior notice on this action is unnecessary because it merely amends regulations to incorporate statutory requirements and makes several technical corrections to 23 CFR part 658. This document also contains several interpretations and general

statements of policy that are not subject to notice and comment under the Administrative Procedure Act. For the reasons set forth here, the FHWA has determined that it has good cause under 5 U.S.C. 553(d)(3) to make the rule effective upon publication in the **Federal Register**.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of E.O. 12866 nor is it considered significant within the meaning of the U.S. Department of Transportation regulatory policies and procedures. The changes reflect statutory requirements and make several technical corrections. It is anticipated that the economic impact of this rulemaking will be minimal. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Most of these rules simply preserve the status quo. Many of the changes benefit truckers, albeit without significant economic consequences, by removing restrictions on their operations or correcting errors that could have led them to inadvertently violate Federal standards. For these reasons, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

This rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rulemaking relates to the Federal-aid Highway Program which is a financial assistance program in which State, local, or tribal governments have authority to adjust their program in accordance with changes made in the program by the Federal government, and thus is excluded from the definition of Federal mandate under the Unfunded Mandates Reform Act of 1995.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this proceeding does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The statutes underlying this rule—primarily the ISTEA and TEA–21—

specify the Department’s role. None of the changes preempts any significant State activity or authority.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

Paperwork Reduction Act

This action does not add or expand a collection of information requirement for purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification 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 contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 658

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

Issued on: December 10, 1998.

Kenneth R. Wykle,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA amends 23 CFR part 658, as set forth below:

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

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

Authority: 23 U.S.C. 127 and 315; 49 U.S.C. 31111–31114; 49 CFR 1.48.

2. In § 658.5, the definitions of “Automobile Transporters” and “Cargo-carrying unit” are revised to read as follows:

§ 658.5 Definitions.

Automobile transporters. Any vehicle combination designed and used specifically for the transport of

assembled highway vehicles, including truck camper units.

* * * * *

Cargo-carrying unit. As used in this part, cargo-carrying unit means any portion of a commercial motor vehicle (CMV) combination (other than a truck tractor) used for the carrying of cargo, including a trailer, semitrailer, or the cargo-carrying section of a single-unit truck. The length of the cargo carrying units of a CMV with two or more such units is measured from the front of the first unit to the rear of the last [including the hitch(es) between the units].

* * * * *

3. In § 658.13, paragraph (b)(3) is revised to read as follows:

§ 658.13 Length.

* * * * *

(b) * * *

(3) No State shall impose an overall length limitation on commercial vehicles operating in truck tractor-semitrailer or truck tractor-semitrailer-trailer combinations.

* * * * *

4. In § 658.17, paragraphs (i) and (k) are revised to read as follows:

§ 658.17 Weight.

* * * * *

(i) The provisions of paragraphs (b), (c), and (d) of this section shall not apply to single-, or tandem-axle weights, or gross weights legally authorized under State law on July 1, 1956. The group of axles requirement established in this section shall not apply to vehicles legally grandfathered under State groups of axles tables or formulas on January 4, 1975. Grandfathered weight limits are vested on the date specified by Congress and remain available to a State even if it chooses to adopt a lower weight limit for a time.

* * * * *

(k) Any vehicle which is regularly and exclusively used as an intrastate public agency transit passenger bus is excluded from the axle weight limits in paragraphs (c) through (e) of this section until October 1, 2003.

* * * * *

Appendix A to Part 658 [Amended]

5. Appendix A to part 658 is amended for the State of Florida by removing the note at the end of the listing for that State.

Appendix C to Part 658 [Amended]

6. Appendix C to part 658 is amended in the listing for the State of Utah for the combination "Truck-trailer-trailer" under the heading of "ROUTES" by

removing the phrase, "combination with a cargo carrying length greater than 85 feet."

[FR Doc. 98-33760 Filed 12-21-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 08-98-018]

RIN 2115-AE46

Special Local Regulations; Eighth Coast Guard District Annual Marine Events

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising Table 1, its list of annual marine events that occur within the Eighth Coast Guard District. This action is being taken to ensure the safety of life and property during each event, while avoiding the necessity of publishing a separate temporary regulation each year for each event. Table 1 reflects the approximate dates and locations of each annual recurring marine event.

DATES: This final rule will become effective February 22, 1999.

FOR FURTHER INFORMATION CONTACT: Project Attorney, Lieutenant Commander Jim Wilson at Commander (dl), Eighth Coast Guard District, 501 Magazine Street, New Orleans, LA 70130-3396, (504) 589-6188.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was published on Tuesday, June 16, 1998, (63 FR 32774) in the **Federal Register** proposing to revise Table 1 to 33 CFR 100.801, the list of annual marine events that occur within the Eighth Coast Guard District. That proposal also noted the revision would include the territories previously encompassed by the Second Coast Guard District as a result of the Eighth Coast Guard District's absorption of the Second Coast Guard District. The Coast Guard received no comments on the proposed rulemaking. A public hearing was not requested and one was not held.

Background and Purpose

This rulemaking updates the existing list of anticipated annual marine events in the Eighth Coast Guard District. This revision also reflects the Eighth Coast Guard District's absorption of the territories previously encompassed by

the Second Coast Guard District. It does so by deleting 33 CFR § 100.201, the list of annual marine events in the old Second Coast Guard District, and by expanding 33 CFR § 100.801 to include both territories.

Regulatory Evaluation

This rule is not a significant regulator action under section 3(f) of Executive Order 12866 and did not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT was unnecessary. The economic impact is not significant because this rule serves only to update an already existing list of marine events and does not change the process for reviewing such occurrences.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned, operated, and not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The segment of the listed waterways regulated is the minimum necessary to assure the safety of life and property on or adjacent to navigable waters. These regulations are relatively brief in duration and will only affect marine traffic. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

No information is collected under this rule. This rule complies with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

Federalism Implications

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications