21 CFR Part 510
New Animal Drugs; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name of approved applications from Animal Sciences Division of Monsanto Co. to Protiva, A Unit of Monsanto Co.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Judith M. O’Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: Animal Sciences Division of Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167, has informed FDA of a change of sponsor name to Protiva, A Unit of Monsanto Co. Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

PART 510—NEW ANIMAL DRUGS

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


2. Section 510.600 is amended in the table in paragraph (c)(5) by alphabetically adding a new entry under "Substances Limitations" to reflect a change of sponsor name.

§ 510.600 [Amended]

2. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) by removing the entry for “Animal Sciences Division of Monsanto Co.” and by alphabetically adding a new entry for “Protiva, A Unit of Monsanto Company,” and in the table in paragraph (c)(2) in the entry for “059946” by removing the sponsor name “Animal Sciences Division of Monsanto Co.” and adding in its place “Protiva, A Unit of Monsanto Company.”
The term "transportation" is added to the definition of "State certification" to conform to the definition of "State highway/transportation agency." 

Section 640.105  Effect of Certification Acceptance
Paragraph (d) is revised to eliminate the listing of fundamental provisions of law in title 23, U.S.C. The listing has become outdated and is subject to periodic changes. This does not change the finding required in 23 U.S.C. 106 that Federal-aid projects under CA will be carried out in accordance with State laws, regulations, directives and standards which will accomplish the policies and objectives issued pursuant to title 23, U.S.C.

Section 640.107  Coverage
Paragraphs (a) and (c) are revised to conform to the language in the ISTEA and 23 U.S.C. 135, Statewide Planning, is added for the projects listed in paragraph (b) and excluded from coverage under CA.

Paragraph (d) is eliminated because it allowed a simplified CA application procedure based on evaluation of the State's operations and performance under the SRP which has been eliminated. The simplified procedure is not needed because the special rules in 23 U.S.C. 106, provided under the ISTEA, allow increased flexibility in approval of projects using Federal-aid funds on non-NHS projects, low-cost NHS projects, and 3R projects on the NHS.

Section 640.109  Requirements for Certification Acceptance
Paragraphs (a) and (b) are revised and combined into a new paragraph (a) to simplify and streamline reviews and to eliminate redundant or unnecessary requirements. The detailed list of title 23 requirements is eliminated and the itemized evaluation of a State's performance and resources, to be used to determine the State's capability to carry out project responsibilities, is replaced by a more flexible approach. The approach is based on process reviews and evaluations conducted as part of the overall FHWA evaluation of the State's performance and resources. Procedures to accept limited-coverage CA, based on an evaluation of operations and performance under an approved SRP, are eliminated because of the repeal of the secondary road system by the ISTEA and because the limited-coverage of projects is not necessary given the special rules provided for in the ISTEA which have replaced the need for CA of such projects.

Paragraph (c) is redesignated as paragraph (b).

Section 640.111  Content of State Certification
Paragraph (a) is revised to eliminate the procedures for limited-coverage State certification which are no longer applicable. Such certification is not necessary for non-NHS projects, low-cost NHS projects, and 3R projects on the NHS under the provisions of 23 U.S.C. 106.

Section 640.113  Procedures
The text is revised and rearranged to simplify and streamline the procedures and eliminate redundant and unnecessary requirements. The revision implements guidance issued by the FHWA for program oversight in conformance with the ISTEA provisions, giving greater flexibility to the administration of Federal-aid projects.

Paragraph (a) is eliminated as redundant and because its subject is covered in § 640.105(d). Paragraph (b) is redesignated as paragraph (a). Paragraph (c) is redesignated as paragraph (b) and the text revised to conform to current FHWA guidance on processing design exceptions for projects administered under CA. Paragraph (d) is redesignated as paragraph (c) and the information on project agreements is updated to the requirements in 23 CFR Part 630, subpart C. Paragraph (e) and Appendix A, referenced in paragraph (e), are eliminated because the listing in Appendix A is outdated and not all inclusive and because the reports required by Appendix A on Federal-aid projects are subject to periodic changes. Paragraph (f) is redesignated as paragraph (d) and the text is revised to conform to the ISTEA provision for acceptance of Federal-aid projects. Paragraph (g) is redesignated as paragraph (e) and the text revised to remove the requirement that the State submit the final voucher on a specific form known as "FHWA 1447." Paragraph (h) is redesignated as paragraph (f).

Section 640.115  Evaluations
Paragraphs (a) and (b) are revised to provide more flexibility in administering the CA procedures, in keeping with the spirit of ISTEA and recommendations made in the 1993 report by the Office of Program Review, entitled "Stewardship Under ISTEA Program Efficiencies." Paragraph (a) is revised to provide that evaluations will be periodic on an "appropriate" basis, rather than requiring evaluations at least once every 4 years.
Paragraph (b) retains the requirement that an evaluation report, with recommendations, be prepared when a State fails to comply with CA requirements. This evaluation report is retained to provide a means for determining whether acceptance of a State’s certification should be rescinded.

Section 640.117 Recision of State Certification

The text is not changed in this section.

Review Procedure

Based on an analysis of public comments received, the FHWA will reexamine its determination that this interim final rule is acceptable as the basis for CA and whether further change is warranted.

Rulemaking Analysis and Notices

The Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., allows agencies engaged in rulemaking to dispense with prior notice and opportunity for comment when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest. For the reasons set forth below, the FHWA has determined that prior notice to the public on this action is unnecessary and contrary to the public interest.

The FHWA has determined that prior notice and opportunity for comment are unnecessary because the changes being adopted in this rulemaking involve streamlining and provide more administrative flexibility in the use of the regulation. This revision, as part of the government regulatory review effort, updates and simplifies the existing CA regulation. This rule provides a less burdensome system for gathering information from the States with respect to the CA process and provides more flexible reporting arrangements for States that are, at their option, participating in the CA program. The previous requirements for periodic reports are deleted. Instead, the States may be requested by the FHWA to furnish reports and information from time to time. Overall, the CA procedures are relaxed and do not impose any additional restrictions on the public.

The FHWA has also determined that prior notice and opportunity for comment would be contrary to the public interest. As noted earlier, the adoption of this interim final rule would allow a timely use by SHAs of the streamlined and simplified CA procedures. Through the streamlined process and simplified reporting requirements, States that have chosen to participate in the CA program can do so to administer their State highway programs more efficiently.

Furthermore, the FHWA has also determined that prior notice and opportunity for comment are not required under the Department of Transportation’s Regulatory Policies and Procedures because it is not anticipated that such action will result in the receipt of useful information.

The APA, according to 5 U.S.C. 553(d)(3), also allows agencies, upon a finding of good cause, to make a rule effective immediately and avoid the 30-day delayed effective requirement. The FHWA has determined that good cause exists to make this rule effective upon publication because the rule streamlines the CA process and provides less prescriptive requirements for its use. Making this rule effective upon publication will enable the States to take advantage of the simplified procedures immediately. Moreover, it should be noted that participation by the States in the CA program is voluntary.

Nevertheless, public comment is solicited on this action. Comments received will be carefully considered in evaluating whether any change to this action is needed.

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 Executive Order 12866 or significant within the meaning of Department of Transportation Regulatory Policies and Procedures. As stated, this revised regulation merely streamlines and updates the current CA regulation by giving added flexibility to the States in their use of CA. It is anticipated that the economic impact of the rulemaking will be minimal; therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the FHWA has evaluated the effects of this rule on small entities. Based on the evaluation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. The FHWA made this determination based on the fact that the interim final rule for CA is an update of a current regulation and will provide greater flexibility in using the CA alternate procedures in the administration of projects consistent with the provisions of ISTEA.

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 action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. This rule does not impose additional costs or burdens on the States, including the likely source of funding for the States, nor does it affect the ability of the States to discharge traditional State government functions. The intent of this rule is to provide the States with additional administrative flexibility in the use of the regulation.

Executive Order 12372 (Intergovernmental Review)

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.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

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 number 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 640

Government procurement, Grant programs—transportation, Highways and roads.


Rodney E. Slater, Federal Highway Administrator.

For the reasons set out above, the FHWA amends chapter I of title 23, Code of Federal Regulations, by revising part 640 to read as set forth below.
PART 640—CERTIFICATION ACCEPTANCE

§ 640.101 Purpose.

The purpose of this part is to provide instructions for preparation and acceptance of State certification proposals to accomplish the policies and objectives of title 23, U.S.C., using State laws, regulations, directives, and standards. Also covered are procedures for administering projects under certification acceptance and evaluating State performance.

§ 640.103 Definitions.

Unless otherwise specified in this part, the definitions in 23 U.S.C. 101(a) are applicable to this part. As used in this part:

Certification acceptance (CA) means the alternative procedure authorized by 23 U.S.C. 117(a) for administering Federal-aid highway projects not on the Interstate System.

State certification means a written statement prepared by a State highway/transportation agency setting forth the laws, regulations, directives, and standards it will use, or cause to be used, in the administration of certain highway projects.

State highway/transportation agency has the same meaning as that given for State highway department in 23 U.S.C. 101.

§ 640.105 Effect of certification acceptance.

(a) Acceptance of a State certification permits a State to discharge certain responsibilities otherwise assigned to the Secretary under title 23, U.S.C., for Federal-aid highway projects. A State may permit performance and project certification by capable local governments.

(b) A acceptance of a State certification does not constitute a commitment or obligation of Federal funds.

(c) Acceptance of a State certification does not preclude FHWA access to and review of a Federal-aid project at any time.

(d) Certification acceptance as an alternative procedure does not replace the fundamental provisions of law in title 23, U.S.C., with respect to the basic structure of the Federal-aid highway program. Acceptance of a CA proposal does not preclude application of any provision of title 23, U.S.C., that may be advantageous to the State.

(e) Nothing in this part shall affect or discharge any responsibility or obligation of the FHWA under any Federal law other than title 23, U.S.C.

§ 640.107 Coverage.

(a) Certification acceptance may apply to Federal-aid highway projects except projects on the Interstate System. If other FHWA regulations and title 23, U.S.C., allow, projects not on a Federal-aid highway may be administered under the provisions of an accepted State certification.

(b) The CA procedure shall not apply to transportation planning and research (23 U.S.C. 134, 135, and 307), highway safety (chapter 4, title 23, U.S.C.), or those public transportation projects not administered by FHWA under title 23, U.S.C.

(c) A State certification may provide for either full or partial coverage of the Federal-aid highway projects, programs, phases of work, and classes of projects.

§ 640.109 Requirements for certification acceptance.

(a) Acceptance of either a full or partial coverage State certification as described in § 640.107(c) will be based upon:

1. A State request and identification of the State laws, regulations, directives, and standards that either separately or collectively will accomplish the policies and objectives contained in or issued pursuant to title 23, U.S.C., and

2. An FHWA finding that the State highway/transportation agency has the capability to carry out project responsibilities in accordance with such State requirements. The FHWA finding will be based on previous process reviews and evaluations conducted as part of FHWA’s oversight of Federal-aid programs and an FHWA evaluation of the State’s performance and resources. If information from process reviews and that available from previous evaluations are considered to be insufficient to form a reasonable judgment, they may be supplemented by additional reviews and inquiries of the State agency.

(b) A State certification may be accepted in whole or in part, depending on FHWA findings. Where minor deficiencies are found, acceptance may be conditioned or may exclude the affected State operations until the deficiencies are corrected. Where deficiencies are found which are of such magnitude as to create doubt that the policies and objectives of title 23, U.S.C., would be accomplished, the State certification will not be accepted until the deficiencies are corrected.

§ 640.111 Content of State certification.

(a) The State certification will include the following:

1. The name of the State highway/transportation agency and the legal authority which permits such agency to accomplish the policies and objectives contained in or issued pursuant to title 23, U.S.C.;

2. A statement of the programs, phases of work, and classes of projects or combinations thereof that the State is including in the certification being submitted for acceptance;

3. For submissions providing full or partial coverage of projects as provided in § 640.107(c), a listing of the title 23, U.S.C., policies and objectives and citation of State laws, regulations, directives, and standards that will be applied. Any policies and objectives that are not applicable due to partial coverage may be omitted; and

4. A description of the State’s methods for assuring local government knowledge of and compliance with State and Federal requirements where they will perform services on projects administered under CA.

(b) Existing assurances and formal agreements between the State and the FHWA with respect to equal employment opportunity, current billing, and control of outdoor advertising will continue in full force and effect and may be incorporated by reference. Likewise, the State’s procedures accepted under 23 U.S.C. 109(h) may be incorporated by reference.

(c) State certifications are to be signed by the chief official of the State highway/transportation agency and submitted to the FHWA Division Administrator.

§ 640.113 Procedures.

(a) Authorization by the FHWA to proceed with work on a CA project will be in response to a written request from the State highway/transportation agency.

(b) If the State finds that exceptions to CA procedures or standards are appropriate on a project, the State will justify and document such decisions.

(c) A project agreement, or modification to a project agreement, will be executed as required by 23 CFR Part 630, subpart C, Project Agreements.

(d) The FHWA may accept projects based on inspections of a type and frequency necessary to ensure the projects are completed in accordance with the Federal standards and requirements.
with appropriate standards. The State is to notify the FHWA when a project is complete and/or ready for such inspection.

(e) Final vouchers will be submitted to the FHWA with the State certifying that the plans, design, and construction for the project were in accord with the laws, regulations, directives, and standards contained in the State certification or such project exceptions as were approved by the FHWA.

(f) Revisions or amendments to State certifications will be made when necessary and processed as provided in § 640.111(c). The existing State certification is to be reviewed periodically to determine its adequacy in light of this part, the statutes in effect at the time of the review, and the operational reviews made by FHWA.

§ 640.115 Evaluations.
(a) The FHWA may conduct periodic evaluations, as deemed appropriate, of the State's operations under CA. These evaluations may include coverage of any or all areas of the State's administration of CA projects.
(b) If a failure to comply with Federal or State laws occurs and the State is unable or unwilling to effect corrective action of the deficiency, an evaluation report, including recommendations, will be prepared by the FHWA as a basis for considering whether acceptance of the State certification should be rescinded under § 640.117.

§ 640.117 Rescission of State Certification.
The acceptance of a State certification may be rescinded at any time upon request of the State or if considered necessary by the FHWA to protect the Federal interest. The rescission may be applied to all or part of the programs or projects covered in the State certification.

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DEPARTMENT OF LABOR
Wage and Hour Division
29 CFR Part 697
Industries in American Samoa; Wage Order
AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.
ACTION: Final rule.
SUMMARY: Under the Fair Labor Standards Act (FLSA), minimum wage rates in American Samoa are set by a special industry committee appointed by the Secretary of Labor. This document puts into effect the minimum wage rates recommended for various industry categories by Industry Committee No. 21, which met in Pago Pago, American Samoa during the week of June 12, 1995. The new minimum wage rates are effective 15 days after their publication in the Federal Register.

EFFECTIVE DATE: This rule is effective on September 28, 1995.

FOR FURTHER INFORMATION CONTACT: Daniel F. Sweeney, Deputy Assistant Administrator, Wage and Hour Division, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–3028, Washington, DC 20210; telephone: (202) 219–8353. This is not a toll free number.

SUPPLEMENTARY INFORMATION:
I. Paperwork Reduction Act
There are no reporting or recordkeeping requirements contained in this rule.

II. Background
Pursuant to sections 5, 6, and 8 of the Fair Labor Standards Act of 1938 (52 Stat. 1062, 1064), as amended (29 U.S.C. 205, 206, 208) and Reorganization Plan No. 6 of 1950 (3 CFR 1949–53 Comp., P. 1004), and by means of Administrative Order No. 662 (60 FR 19099), the Secretary of Labor appointed and convened Industry Committee No. 21 for Industries in American Samoa. The Committee filed with the Administrator a report, containing the Secretary’s findings of fact and recommendations with respect to minimum wages for various industry classifications.

As required by the Secretary’s notice, Industry Committee No. 21 conducted an investigation and hearing in Pago Pago, American Samoa during the week of June 12, 1995. Subsequently, the Committee filed with the Administrator of the Wage and Hour Division a report, dated June 19, 1995, containing its findings of fact and recommendations with respect to minimum wages for various industry classifications.

A accordingly, as authorized and required by section 8 of the Fair Labor Standards Act of 1938, Reorganization Plan No. 6 of 1950 and 29 CFR 511.18, this rule revises § 697.1 and 697.3 of 29 CFR Part 697 to implement the recommendations of Industry Committee No. 21.

Executive Order 12866/Section 202 of the Unfunded Mandates Reform Act of 1995
This rule is not a "significant regulatory action" within the meaning of Executive Order 12866, and no regulatory impact analysis is required. This rule puts into effect the wage rates recommended by Industry Committee No. 21 that met in Pago Pago, American Samoa during the week of June 12, 1995. The Committee recommended increases in various industry categories, ranging from 5 cents per hour for fish canning and processing and can manufacturing, the largest private industry in American Samoa, the 35 cents per hour, in two steps, in finance and insurance and private hospitals and educational institutions. When these increases are fully implemented, wage rates will range from $2.45 an hour (government and miscellaneous industries) to $3.75 an hour, shipping and transportation, classification A (stevedoring, lighterage, and maritime shipping agency). There are approximately 16,000 employees in the various industry classifications. Based on the number of workers whose wages must be increased to the new minimum wage level in 1995 and/or 1996, and assuming that employees currently paid at or in excess of the new minimum wage will also receive commensurate wage increases to maintain relative pay comparability, increases in the overall annual wage bill are expected to be modest—approximately $7 million in 1995 and $5 million in 1996. Thus, this rule is not expected to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

For similar reasons, the rule does not require a § 202 statement under the Unfunded Mandates Reform Act of 1995. In this regard, wage order procedures under 29 CFR Part 511 require residents of American Samoa to be included in the composition of any industry committee. Individuals are