DEA amended 21 CFR 1309.29 to exempt retail distributors of pseudoephedrine and phenylpropanolamine related drug products from the registration requirement, so long as they engaged exclusively in distributions of regulated drug products below the 24-gram limit in a single transaction for legitimate medical use, either directly to walk-in customers or in face-to-face transactions by direct sales. The second exemption dealt with persons who are required to obtain a registration. The interim rule amended 21 CFR 1310.09 to provide that any person who submitted an application for registration for activities involving pseudoephedrine and phenylpropanolamine regulated drug products on or before December 3, 1997, was exempted from the registration requirement for their lawful activities with regulated drug products until the Administration takes final action with respect to that application.

No comments were received regarding this interim rulemaking. Therefore, the interim rule is adopted without change.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that this final rulemaking will not have a significant economic impact upon a substantial number of small business entities whose interest must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This final rulemaking is an administrative action to make the regulations consistent with the law and to avoid interruption of legitimate commerce by granting temporary exemptions from registration.

The Deputy Assistant Administrator further certifies that this final rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1–B. DEA has determined that this is not a significant rulemaking action.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. this rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

The interim rule amending 21 CFR parts 1309 and 1310 which was published on October 17, 1997 at 62 FR 53959 is adopted as a final rule.

Dated: June 23, 1999.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 99–19047 Filed 7–26–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

RIN 0906–AA50

National Vaccine Injury Compensation Program: Addition of Vaccines Against Rotavirus to the Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the existing regulations governing the National Vaccine Injury Compensation Program (VICP) by adding vaccines against rotavirus to the Table of Injuries, which lists the vaccines covered under the VICP. This action is taken under section 2114(e) of the Public Health Service Act (the Act). The VICP provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines.

The two prerequisites for adding vaccines against rotavirus to the VICP have been satisfied. An excise tax of 75 cents per dose was enacted on October 21, 1998, and took effect for sales of the vaccines after October 21, 1998. The Centers for Disease Control and Prevention (CDC) has recommended to the Secretary of HHS that this vaccine be routinely administered to children. Thus, vaccines against rotavirus are now included in the VICP.

EFFECTIVE DATE: This regulation is effective on July 27, 1999. As provided by section 13632(a)(3) of Public Law 103–66, the Omnibus Budget Reconciliation Act of 1993, the addition of the vaccines against rotavirus to the VICP took effect on October 22, 1998, the effective date of the excise tax. See the discussion under **SUPPLEMENTARY INFORMATION**, for an explanation of the implications of this applicability date.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Medical Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–4198.

SUPPLEMENTARY INFORMATION: The statute authorizing the VICP provides for the inclusion of additional vaccines in the Program when they are recommended by the CDC to the Secretary for routine administration to children. See section 2114(e) of the Act, 42 U.S.C. 300aa–14(e). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the Program provide that such vaccines will be included in the Table of Injuries when an excise tax to provide funds for the payment of compensation with respect to such vaccines takes effect. 42 CFR 100.3(c)(3) (1998).

The CDC recommendation regarding vaccines against rotavirus was published in the Morbidity and Mortality Weekly Report on March 19, 1999. The excise tax for such vaccines was enacted by Public Law 105–277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, and became effective for sales after October 21, 1998. Accordingly, we are amending the regulations to include specific reference to rotavirus vaccines in the Table of Injuries and in the ''coverage'' portion of the regulations.

We have not identified any illness, disease, injury or condition which is caused by vaccines against rotavirus. Thus, the vaccine is added to the Table of Injuries with ''No Condition Specified.'' If we learn of any such illness, disease, injury or condition, we will consider amending the Table of Injuries to provide for its coverage, and a time period in which the first symptom or manifestation of its onset will be presumed to be vaccine-related.

Section 2116(b) of the Act, 42 U.S.C. 300aa–16(b), provides that individuals who were not previously eligible to file a petition before a revision to the Table of Injuries may file a petition for compensation for a vaccine added to the Table of Injuries. Such a petition must be filed not later than 2 years after the effective date of the revision if the injury or death occurred not more than

8 years before the effective date of the revision. Thus, for injuries or deaths related to rotavirus vaccine which occurred before October 22, 1998, petitions may be filed no later than October 22, 2000, provided that the injury or death occurred no earlier than October 22, 1990. Filing deadlines for injuries or deaths related to rotavirus vaccines administered after October 21, 1998, are governed by section 2116(a)(2) and (3) of the Act, 42 U.S.C. 300aa–16(a)(2) and (3).

Justification for Omitting Notice of Proposed Rulemaking

This amendment to 42 CFR 100.3 is required by section 2114(e) of the Act and 42 CFR 100.3, Vaccine injury table. Since this is a technical amendment, the Secretary has determined, under 5 U.S.C. 553 and departmental policy, that it is unnecessary and impractical to follow proposed rulemaking procedures or to delay the effective date of this final rule.

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Department has determined that no resources are required to implement the requirements in this rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities. The Secretary has also determined that this final rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. This technical amendment adds a new item to the Vaccine Injury Table.

We have determined that the rule is not a ''major rule'' within the meaning of the statute providing for Congressional review of agency rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act of 1980

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Dated: July 15, 1999.

Donna E. Shalala,

Secretary.

Accordingly, 42 CFR part 100 is amended as set forth below.

PART 100—VACCINE INJURY COMPENSATION

1. The authority citation for 42 CFR part 100 is revised to read as follows:

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act; 100 Stat. 3767, as revised (42 U.S.C. 300aa–15); § 100.3 Vaccine Injury Table, issued under secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); and sec. 2114(c) and (e) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645 (42 U.S.C. 300aa–14(c) and (e)); and sec. 904(b) of Pub. L. 105–34, 111 Stat. 873.

§ 100.3 [Amended]

2. The Vaccine Injury Table at § 100.3(a) is amended by redesignating Item XII as Item XIII, and by adding a new Item XII as follows:

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
* *	* *	* *
XII. Rotavirus vaccine.	No condition specified.	Not applicable.

§ 100.3 [Amended]

3. Section 100.3(c) is amended as follows:

a. Remove in paragraph (c)(1) the words ''paragraph (c)(2) or (3) of this section'' and add in its place the words ''paragraph (c)(2), (3) or (4) of this section'';

b. Redesignate paragraph (c)(3) as paragraph (c)(4);

c. Remove in paragraph (c)(4), as redesignated, the words ''(Item XII of the Table)'' and add in its place the words ''(Item XIII of the Table)''; and

d. Add a new paragraph (c)(3) to read as follows:

* * * * *

(c) Coverage provisions. * * *

(3) Rotavirus vaccines (Item XII of the Table) are included in the Table as of October 22, 1998.

* * * * *

[FR Doc. 99–19114 Filed 7–26–99; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 828 and 852

RIN 2900–AJ47

VA Acquisition Regulation: Bonds and Insurance

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs Acquisition Regulation to revise and update section numbers and titles to correspond with the Federal Acquisition Regulation, to make minor grammatical corrections and revisions, to allow return of bid guarantees, other than bid bonds, to bidders by any method that will provide evidence of receipt, and to designate the Deputy Assistant Secretary for Acquisition and Materiel Management as the Department's designee for excluding individuals from acting as sureties on bonds and for making determinations to accept bonds from individuals named on the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

DATES: *Effective Date:* July 27, 1999.

FOR FURTHER INFORMATION CONTACT: Don Kaliher, Acquisition Policy Team (95A), Office of Acquisition and Materiel Management, Department of Veterans Affairs, 810 Vermont Ave., NW, Washington DC 20420, (202) 273–8819.

SUPPLEMENTARY INFORMATION: The requirement at 828.101–70 to return bid guarantees, other than bid bonds, by certified mail has been modified to allow any method of delivery that will provide evidence of receipt. This will