This final rule extends a time-limited tolerance that was previously extended by EPA under FFDCSA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, this final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 51735, October 4, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

Since this extension of an existing time-limited tolerance does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

IV. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's Federal Register. This is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.


James Jones,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


§ 180.355 [Amended]

2. In § 180.355, the table to paragraph (b) is amended by changing the date "6/30/98" to read "6/30/99".

[FDOC. 98–12425 Filed 5–8–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 60

RIN 0906–AA49

National Vaccine Injury Compensation Program (VICP): Effective Date Provisions of Coverage of Certain Vaccines to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: Section 904(b) of the Taxpayer Relief Act of 1997 provides for an excise tax for three new vaccines, effective August 6, 1997. Petitions for compensation for injuries or deaths related to hepatitis B, Hib, and varicella vaccines may now be filed under the Vaccine Injury Compensation Program (VICP). This technical amendment amends the Code of Federal Regulations (CFR) to include a date certain (August 6, 1997) in § 100.3(c) of the Vaccine Injury Compensation Program regulations, so that there will be no uncertainty as to the coverage of these three vaccines.

EFFECTIVE DATE: This final rule is effective May 11, 1998.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Medical Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, (301) 443–4198, or David Benor, Senior Attorney, Office of the General Counsel (301) 443–2006.

SUPPLEMENTARY INFORMATION: The National Vaccine Injury Compensation Program (VICP), established by Subtitle 2 of Title XXI of the Public Health Service Act (the Act), provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines. The Vaccine Injury Table (the Table) establishes presumptions about causation of certain illnesses and conditions which are used by the U.S. Court of Federal Claims to adjudicate petitions. The Act provides that a revision to the Table, based on addition of new vaccines under section 2114(e) of the Act, shall take effect upon the effective date of a tax enacted to provide funds for compensation for injuries from vaccines that are added to the Table. (See section 13632(a)(3) of the Omnibus Budget Reconciliation Act of 1993, Public Law 103–66, enacted August 10, 1993.)

On August 5, 1997, the President signed Public Law 105–34, the
“Taxpayer Relief Act of 1997.” Section 904(a) of this Act provides that the excise tax on all covered vaccines under the VICP is 75 cents per dose and that combinations of vaccines are subject to an excise tax which is the sum of the amounts for each vaccine included in the combination. The amendments of the Taxpayer Relief Act also make effective the coverage of three new vaccines under the VICP—huratitis B, H1b, and varicella vaccines.

On October 9, 1997, a Notice was published in the Federal Register (62 FR 52724) announcing the excise tax for these vaccines and that petitions for compensation for injuries or deaths related to hepatitis B, Hib, and varicella vaccines (items VIII, IX, X, and XI of the Table) may now be filed under the VICP. In accordance with section 2116(b) of the PHS Act, for injuries or deaths that occurred before August 6, 1997, these three vaccines, petitions may be filed no later than August 6, 1999, provided that the injury or death occurred no earlier than August 6, 1989.

In accordance with section 904(b) of the Taxpayer Relief Act of 1997 which provides for an excise tax for these three new vaccines, this final rule (technical amendment) amends the CFR to include a date certain (August 6, 1997) in § 100.3(c) of the regulations for the coverage of these three new vaccines. Paragraph (c)(3) provides for inclusion of other new vaccines, as they may be added in the future under item XII of the Table.

Justification for Omitting Notice of Proposed Rulemaking

Since these amendments are of a technical nature, the Secretary has determined, pursuant to 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 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 maximize 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, costs, benefits, incentives, equity, and available information. Regulations that 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 regulation. 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 these regulations 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. This technical amendment sets forth the effective date provision of coverage of certain vaccines to the Vaccine Injury Table. As such, this rule would have no major effect on the economy or on Federal or State expenditures.

Paperwork Reduction Act of 1995

This Final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.


Claude Earl Fox,
Acting Administrator, Health Resources and Services Administration.

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).

2. Section 100.3(c) is amended by revising its title, by adding "or (3)" in the first sentence of paragraph (c)(1) after the words "paragraph (c)(2)" by revising paragraph (c)(2), and by adding a new paragraph (c)(3) to read as follows:

   § 100.3 Vaccine injury table.

   * * * * *