EPA-APPROVED LOUISIANA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA approval date	Explanation
* *	*	*	* *	*
1997 8-Hour Ozone Section 110 Maintenance Plan.	Calcasieu Parish (Lake Charles Area), LA.	7/20/07	10/09/08 [Insert FR page number where document begins].	
1997 8-Hour Ozone Section 110 Maintenance Plan.	St. James Parish, LA	8/24/07	10/09/08 [Insert FR page number where document begins].	

■ 3. Section 52.975, entitled, ''Redesignations and maintenance plans; ozone'', is amended by adding a new paragraph (j) as follows:

§ 52.975 Redesignations and maintenance plans; ozone.

* * * * *

(j) Approval. The Louisiana Department of Environmental Quality (LDEQ) submitted 1997 8-hour ozone NAAQS maintenance plans for the areas of Calcasieu and St. James Parishes on July 20, 2007, and August 24, 2007, respectively. The two areas are designated unclassifiable/attainment for the 1997 8-hour ozone standard. EPA determined these requests for Calcasieu and St. James Parishes were complete on October 5, 2007, and October 16, 2007, respectively. The maintenance plans meet the requirements of section 110(a)(1) of the Clean Air Act, and are consistent with EPA's maintenance plan guidance document dated May 20, 2005. The EPA therefore approved the 1997 8-hour ozone NAAQS maintenance plans for the areas of Calcasieu and St. James Parishes on *October 9, 2008*.

* * * * *

[FR Doc. E8–23867 Filed 10–8–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[EPA–R06–RCRA–2008–0418; SW–FRL–8727–8]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Environmental Protection Agency (EPA) is granting a petition submitted by Lockheed Martin Aeronautics Company to exclude (or delist) the sludge from its wastewater treatment plant generated by Lockheed Martin Aeronautics Company in Fort Worth, Texas from the lists of hazardous wastes. This final rule responds to the petition submitted by Lockheed Martin Aeronautics Company to delist F019 sludge generated from the facility's wastewater treatment plant.

After careful analysis and use of the Delisting Risk Assessment Software (DRAS), EPA has concluded the petitioned waste is not hazardous waste. This exclusion applies to 90 cubic yards per year of the F019 sludge. Accordingly, this final rule excludes the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) when it is disposed in a Subtitle D Landfill.

DATES: *Effective Date:* October 9, 2008.

ADDRESSES: The public docket for this final rule is located at the Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202, and is available for viewing in EPA Freedom of Information Act review room on the 7th floor from 8 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. Call (214) 665–6444 for appointments. The reference number for this docket is EPA–R06–RCRA–2008–0418. The public may copy material from any regulatory docket at no cost for the first 100 pages and at a cost of $0.15 per page for additional copies.

FOR FURTHER INFORMATION CONTACT: Ben Banipal, Section Chief of the Corrective Action and Waste Minimization Section, Multimedia Planning and Permitting Division (6PD–C), Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202.

For technical information concerning this notice, contact Wendy Jacques, Environmental Protection Agency Region 6, 1445 Ross Avenue, (6PD–F), Dallas, Texas 75202, at (214) 665–7395, or *jacques.wendy@epa.gov.*

SUPPLEMENTARY INFORMATION: The information in this section is organized as follows:

I. Overview Information
A. What action is EPA finalizing?
B. Why is EPA approving this action?
C. What are the limits of this exclusion?
D. How will Lockheed Martin Aeronautics Company manage the waste if it is delisted?
E. When is the final delisting exclusion effective?
F. How does this final rule affect states?
II. Background
A. What is a delisting?
B. What regulations allow facilities to delist a waste?
C. What information must the generator supply?
III. EPA's Evaluation of the Waste Information and Data
A. What waste did Lockheed Martin Aeronautics Company petition EPA to delist?
B. How much waste did Lockheed Martin Aeronautics Company propose to delist?
C. How did Lockheed Martin Aeronautics Company sample and analyze the waste data in this petition?
IV. Public Comments Received on the proposed exclusion
Who submitted comments on the proposed rule?
V. Statutory and Executive Order Reviews

I. Overview Information

A. What action is EPA finalizing?

After evaluating the petition, EPA proposed, on May 19, 2008, to exclude the wastewater treatment plant sludge from the lists of hazardous waste under 40 CFR 261.31 and 261.32 (see 70 FR 41358). EPA is finalizing the decision to grant Lockheed Martin Aeronautics Company's delisting petition to have its waste water treatment sludge managed and disposed as non-hazardous waste provided certain verification and monitoring conditions are met.

B. Why is EPA approving this action?

Lockheed Martin Aeronautics Company's petition requests a delisting from the F019 waste listing under 40 CFR 260.20 and 260.22. Lockheed Martin Aeronautics Company does not

believe that the petitioned waste meets the criteria for which EPA listed it. Lockheed Martin Aeronautics Company also believes no additional constituents or factors could cause the waste to be hazardous. EPA's review of this petition included consideration of the original listing criteria and the additional factors required by the Hazardous and Solid Waste Amendments of 1984. See section 3001(f) of RCRA, 42 U.S.C. 6921(f), and 40 CFR 260.22 (d)(1)–(4) (hereinafter all sectional references are to 40 CFR unless otherwise indicated). In making the final delisting determination, EPA evaluated the petitioned waste against the listing criteria and factors cited in § 261.11(a)(2) and (a)(3). Based on this review, EPA agrees with the petitioner that the waste is non-hazardous with respect to the original listing criteria. If EPA had found, based on this review, that the waste remained hazardous based on the factors for which the waste as originally listed, EPA would have proposed to deny the petition. EPA evaluated the waste with respect to other factors or criteria to assess whether there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. EPA considered whether the waste is acutely toxic, the concentration of the constituents in the waste, their tendency to migrate and to bioaccumulate, their persistence in the environment once released from the waste, plausible and specific types of management of the petitioned waste, the quantities of waste generated, and waste variability. EPA believes that the petitioned waste does not meet the listing criteria and thus should not be a listed waste. EPA's final decision to delist waste from Lockheed Martin Aeronautics Company's facility is based on the information submitted in support of this rule, including descriptions of the wastes and analytical data from the Fort Worth, Texas facility.

C. What are the limits of this exclusion?

This exclusion applies to the waste described in the petition only if the requirements described in 40 CFR part 261, Appendix IX, Table 1 and the conditions contained herein are satisfied.

D. How will Lockheed Martin Aeronautics Company manage the waste if it is delisted?

The sludge from Lockheed Martin Aeronautics Company will be disposed of in a RCRA Subtitle D landfill.

E. When is the final delisting exclusion effective?

This rule is effective October 9, 2008. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of RCRA, 42 U.S.C. 6930(b)(1), allows rules to become effective less than six months after the rule is published when the regulated community does not need the six-month period to come into compliance. That is the case here because this rule reduces, rather than increases, the existing requirements for persons generating hazardous waste. This reduction in existing requirements also provides a basis for making this rule effective immediately, upon publication, under the Administrative Procedure Act, pursuant to 5 U.S.C. 553(d).

F. How does this final rule affect states?

Because EPA is issuing this exclusion under the Federal RCRA delisting program, only states subject to Federal RCRA delisting provisions would be affected. This would exclude states which have received authorization from EPA to make their own delisting decisions.

EPA allows states to impose their own non-RCRA regulatory requirements that are more stringent than EPA's, under section 3009 of RCRA, 42 U.S.C. 6929. These more stringent requirements may include a provision that prohibits a Federally issued exclusion from taking effect in the state. Because a dual system (that is, both Federal (RCRA) and State (non-RCRA) programs) may regulate a petitioner's waste, EPA urges petitioners to contact the State regulatory authority to establish the status of their wastes under the State law.

EPA has also authorized some states (for example, Louisiana, Oklahoma, Georgia, and Illinois) to administer an RCRA delisting program in place of the Federal program; that is, to make state delisting decisions. Therefore, this exclusion does not apply in those authorized states unless that state makes the rule part of its authorized program. If Lockheed Martin Aeronautics Company transports the petitioned waste to or manages the waste in any state with delisting authorization, Lockheed Martin Aeronautics Company must obtain delisting authorization from that state before it can manage the waste as non-hazardous in the state.

II. Background

A. What is a delisting petition?

A delisting petition is a request from a generator to EPA, or another agency with jurisdiction, to exclude or delist from the RCRA list of hazardous waste, certain wastes the generator believes should not be considered hazardous under RCRA.

B. What regulations allow facilities to delist a waste?

Under §§ 260.20 and 260.22, facilities may petition EPA to remove their wastes from hazardous waste regulation by excluding them from the lists of hazardous wastes contained in §§ 261.31 and 261.32. Specifically, § 260.20 allows any person to petition the Administrator to modify or revoke any provision of 40 CFR parts 260 through 265 and 268. Section 260.22 provides generators the opportunity to petition the Administrator to exclude a waste from a particular generating facility from the hazardous waste lists.

C. What information must the generator supply?

Petitioners must provide sufficient information to EPA to allow EPA to determine that the waste to be excluded does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the Administrator must determine, where he/she has a reasonable basis to believe that factors (including additional constituents) other than those for which the waste was listed could cause the waste to be a hazardous waste and that such factors do not warrant retaining the waste as a hazardous waste.

III. EPA's Evaluation of the Waste Information and Data

A. What waste did Lockheed Martin Aeronautics Company petition EPA to delist?

On February 21, 2006, Lockheed Martin Aeronautics Company petitioned EPA to exclude from the lists of hazardous wastes contained in § 261.31, sludge (F019) generated from its facility located in Forth Worth, Texas. The waste falls under the classification of listed waste pursuant to § 261.31.

B. How much waste did Lockheed Martin Aeronautics Company propose to delist?

Specifically, in its petition, Lockheed Martin Aeronautics Company requested that EPA grant a standard exclusion for 90 cubic yards per year of sludge resulting from the treatment of waste waters from the manufacturing processes at its facility.

C. How did Lockheed Martin Aeronautics Company sample and analyze the waste data in this petition?

To support its petition, Lockheed Martin Aeronautics Company submitted:

- Analytical results of the toxicity characteristic leaching procedure and total constituent analysis for volatile

and semi volatile organics, pesticides, herbicides, dioxins/furans, PCBs and metals for six sludge samples;

- Analytical results from multiple pH leaching of metals; and
- Descriptions of the wastewater treatment process.

IV. Public Comments Received on the Proposed Exclusion

Who submitted comments on the proposed rule?

No comments were received on the Proposed Rule.

V. Statutory and Executive Order Reviews

Under Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), this rule is not of general applicability and therefore is not a regulatory action subject to review by the Office of Management and Budget (OMB). This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it applies to a particular facility only. Because this rule is of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202, 204, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Because this rule will affect only a particular facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA. Because this rule will affect only a particular facility, this final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, ''Federalism'', (64 FR 43255, August 10, 1999). Thus, Executive Order 13132 does not apply to this rule. Similarly, because this rule will affect only a particular facility, this final rule does not have tribal implications, as specified in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this rule. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The basis for this belief is that the Agency used the DRAS program, which considers health and safety risks to infants and children, to calculate the maximum allowable concentrations for this rule. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866. This rule does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988, ''Civil Justice Reform'', (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report which includes a copy of the rule to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability.

Lists of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f)

Dated: October 1, 2008.

Bill Luthans,

Acting Director, Multimedia Planning and Permitting Division, Region 6.

■ For the reasons set out in the preamble, 40 CFR part 261 is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

■ 2. In Table 1 of Appendix IX of Part 261 add the following waste stream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Waste Excluded Under §§ 260.20 and 260.22

TABLE 1—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * *
Lockheed Martin Aeronautics Company.	Fort Worth, TX	Sludge (EPA Hazardous Waste Number F019) generated at a maximum rate of 90 cubic yards per calendar year after October 9, 2008. For the exclusion to be valid, Lockheed Martin Aeronautics Company must implement a verification testing program that meets the following Paragraphs: (1) Delisting Levels: All concentrations for those constituents must not exceed the maximum allowable concentrations in mg/l specified in this paragraph. Sludge Leachable Concentrations (mg/l): Antimony—8.45; Arsenic—0.657; Barium—100.0; Cadmium—1.00; Chromium—5.0; Chromium, Hexavalent—5.0; Cobalt—1040; Copper—1810; Cyanide—240; Lead—5.0; Mercury—0.20; Nickel—1040; Selenium—1.0; Silver—5.0; Vanadium—51.5; Zinc—15800; Acetone—40600; Acetonitrile—766; Carbon Disulfide—4400; Ethylbenzene—846; Methyl Ethyl Ketone—200.0; Methyl Isobutyl Ketone—3610; Methylene Chloride—6.16; Toluene—1180; Xylenes—745. (2) Waste Holding and Handling:

TABLE 1—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(A) Waste classification as non-hazardous can not begin until compliance with the limits set in paragraph (1) for sludge has occurred for two consecutive quarterly sampling events. (B) If constituent levels in any sample taken by Lockheed Martin Aeronautics Company exceed any of the delisting levels set in paragraph (1) for the sludge, Lockheed Martin Aeronautics Company must do the following: (i) notify EPA in accordance with paragraph (6) and (ii) manage and dispose the sludge as hazardous waste generated under Subtitle C of RCRA. (3) Testing Requirements: Upon this exclusion becoming final, Lockheed Martin Aeronautics Company may perform quarterly analytical testing by sampling and analyzing the sludge as follows: (A) Quarterly Testing: (i) Collect two representative composite samples of the sludge at quarterly intervals after EPA grants the final exclusion. The first composite samples may be taken at any time after EPA grants the final approval. Sampling should be performed in accordance with the sampling plan approved by EPA in support of the exclusion. (ii) Analyze the samples for all constituents listed in paragraph (1). Any composite sample taken that exceeds the delisting levels listed in paragraph (1) for the sludge must be disposed as hazardous waste in accordance with the applicable hazardous waste requirements. (iii) Within thirty (30) days after taking each quarterly sample, Lockheed Martin Aeronautics Company will report its quarterly analytical test data to EPA. If levels of constituents measured in the samples of the sludge do not exceed the levels set forth in paragraph (1) of this exclusion for two consecutive quarters or sampling events, Lockheed Martin Aeronautics Company can manage and dispose the non-hazardous sludge according to all applicable solid waste regulations. (B) Annual Testing: (i) If Lockheed Martin Aeronautics Company completes the quarterly testing specified in paragraph (3) above and no sample contains a constituent at a level which exceeds the limits set forth in paragraph (1), Lockheed Martin Aeronautics Company may begin annual testing as follows: Lockheed Martin Aeronautics Company must test two representative composite samples of the sludge for all constituents listed in paragraph (1) at least once per calendar year. (ii) The samples for the annual testing shall be a representative composite sample according to appropriate methods. As applicable to the method-defined parameters of concern, analyses requiring the use of SW–846 methods incorporated by reference in 40 CFR 260.11 must be used without substitution. As applicable, the SW–846 methods might include Methods 0010, 0011, 0020, 0023A, 0030, 0031, 0040, 0050, 0051, 0060, 0061, 1010A, 1020B, 1110A, 1310B, 1311, 1312, 1320, 1330A, 9010C, 9012B, 9040C, 9045D, 9060A, 9070A (uses EPA Method 1664, Rev. A), 9071B, and 9095B. Methods must meet Performance Based Measurement System Criteria in which the Data Quality Objectives are to demonstrate that samples of the Lockheed Martin Aeronautics Company sludge are representative for all constituents listed in paragraph (1). (iii) The samples for the annual testing taken for the second and subsequent annual testing events shall be taken within the same calendar month as the first annual sample taken. (iv) The annual testing report should include the total amount of waste in cubic yards disposed during the calendar year. (4) Changes in Operating Conditions: If Lockheed Martin Aeronautics Company significantly changes the process described in its petition or starts any processes that generate(s) the waste that may or could affect the composition or type of waste generated (by illustration, but not limitation, changes in equipment or operating conditions of the treatment process), it must notify EPA in writing and it may no longer handle the wastes generated from the new process as non-hazardous until the wastes meet the delisting levels set in paragraph (1) and it has received written approval to do so from EPA. Lockheed Martin Aeronautics Company must submit a modification to the petition complete with full sampling and analysis for circumstances where the waste volume changes and/or additional waste codes are added to the waste stream. (5) Data Submittals: Lockheed Martin Aeronautics Company must submit the information described below. If Lockheed Martin Aeronautics Company fails to submit the required data within the specified time or maintain the required records on-site for the specified time, EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in paragraph (6). Lockheed Martin Aeronautics Company must: (A) Submit the data obtained through paragraph (3) to the Chief, Corrective Action and Waste Minimization Section, Multimedia Planning and Permitting Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, Texas, 75202, within the time specified. All supporting data can be submitted on CD–ROM or some comparable electronic media. (B) Compile records of analytical data from paragraph (3), summarized, and maintained on-site for a minimum of five years. (C) Furnish these records and data when either EPA or the State of Texas requests them for inspection.

TABLE 1—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(D) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted: ''Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. 1001 and 42 U.S.C. 6928), I certify that the information contained in or accompanying this document is true, accurate and complete. As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. If any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion.'' (6) Reopener: (A) If, anytime after disposal of the delisted waste Lockheed Martin Aeronautics Company possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or ground water monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at level higher than the delisting level allowed by the Division Director in granting the petition, then the facility must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data. (B) If either the quarterly or annual testing of the waste does not meet the delisting requirements in paragraph 1, Lockheed Martin Aeronautics Company must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data. (C) If Lockheed Martin Aeronautics Company fails to submit the information described in paragraphs (5), (6)(A) or (6)(B) or if any other information is received from any source, the Division Director will make a preliminary determination as to whether the reported information requires EPA action to protect human health and/or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (D) If the Division Director determines that the reported information requires action by EPA, the Division Director will notify the facility in writing of the actions the Division Director believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed EPA action is not necessary. The facility shall have 10 days from the date of the Division Director's notice to present such information. (E) Following the receipt of information from the facility described in paragraph (6)(D) or (if no information is presented under paragraph (6)(D)) the initial receipt of information described in paragraphs (5), (6)(A) or (6)(B), the Division Director will issue a final written determination describing EPA actions that are necessary to protect human health and/or the environment. Any required action described in the Division Director's determination shall become effective immediately, unless the Division Director provides otherwise. (7) *Notification Requirements:* Lockheed Martin Aeronautics Company must do the following before transporting the delisted waste. Failure to provide this notification will result in a violation of the delisting petition and a possible revocation of the decision. (A) Provide a one-time written notification to any state Regulatory Agency to which or through which it will transport the delisted waste described above for disposal, 60 days before beginning such activities. (B) Update one-time written notification, if it ships the delisted waste into a different disposal facility. (C) Failure to provide this notification will result in a violation of the delisting variance and a possible revocation of the decision.
*	*	* * * * *

[FR Doc. E8–24009 Filed 10–8–08; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

RIN 0906–AA55

National Vaccine Injury Compensation Program: Removal of Separate Category for Vaccines Containing Live, Oral, Rhesus-Based Rotavirus From the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Interim final rule.

SUMMARY: Through this interim final rule, the Secretary removes the category of vaccines containing live, oral, rhesus-based rotavirus, Category XII, from the Vaccine Injury Table (Table). The Table includes a list of covered vaccines under the National Vaccine Injury Compensation Program (VICP). The VICP provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. This interim final rule is technical in nature. Even prior to the publication of this final rule, Category XII, the category that is being removed from the Table, only applied to vaccines that were administered on or before August 26, 2002. Given the applicable statute of limitations and the fact that Category XII limited its application to vaccines administered on or before August 26, 2002, the Secretary believes that no persons have claims that could be pursued under that category. Petitioners may still be able to file petitions relating to rotavirus vaccines under Category XI of the Table, the category of ''rotavirus vaccines,'' which does not include any associated injuries. Although the Secretary believes that the changes made in this interim final rule are noncontroversial as they do not affect the rights of any potential petitioners with the VICP, the Department is seeking public comment on this interim final rule. Written comments must be submitted on or before November 10, 2008. The Department will consider the comments received and will decide whether to amend the Table based on such comments.

DATES: This regulation is effective November 10, 2008.

ADDRESSES: You may submit written comments, identified by the Regulatory Information Number (RIN) 0906–AA55 by an any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: gevans@hrsa.gov.* Include RIN 0906–AA55 in the subject line of the message.
- *Mail:* Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), Room 11C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.
- *Instructions:* All submissions received must include the agency name and RIN for this rulemaking. All comments received will be available for public inspection and copying without charge, including any personal information provided, at Parklawn Building, 5600 Fishers Lane Room 11C–26, Rockville, Maryland 20857, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–6593.

SUPPLEMENTARY INFORMATION:

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–10 *et seq.*) established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. Under this Federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. In order to gain entitlement to compensation under title XXI of the Public Health Service (PHS) Act for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by proving that the first symptom of an injury/condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and therefore presumed to be caused by a vaccine (unless another cause is found), or by proof of vaccine causation, if the injury/condition is not on the Table or did not occur within the time period specified on the Table.

The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. See section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines. (42 CFR 100.3(c)(5)). The statute authorizing the VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. See sections 2114(c)(3) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(3) and 300aa–14(e)(2).

Because the prerequisites for adding rotavirus vaccines to the VICP occurred, the Secretary published a final rule in the **Federal Register** (FR) on July 27, 1999, adding vaccines against rotavirus to the Table (64 FR 40517). Because the Secretary had not identified any illness, disease, injury or condition caused by vaccines against rotavirus, the category of vaccines was added to the Table with ''[n]o condition specified.'' The Secretary made clear that if he learned of any such illness, disease, injury or condition, he would consider amending the Table.

In a notice of proposed rulemaking published on July 13, 2001, the Secretary announced his findings that the condition of intussusception could reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus (66 FR 36735). Based on those findings, the Secretary proposed amending the Table by adding to the Table vaccines containing live, oral, rhesus-based rotavirus (trade name Rotashield) as a distinct category, with intussusception listed as a covered Table injury. This proposal was based upon the recommendation by the CDC that Rotashield, the only rotavirus vaccine licensed in the United States (U.S.) at the time, no longer be administered to infants in the U.S. based on review of data indicating a strong association between Rotashield and intussusception in the 1 to 2 weeks following vaccination.

In a final rule published July 25, 2002, the Secretary made the changes proposed in the earlier rule (67 FR 48558). After these amendments, the Table included two categories of