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List of Subjects in 40 CFR Part 300

Environmental protection, Hazardous waste.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601-9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580; 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: September 28, 2001.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

RIN 0906-AA55

National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Proposed rule; notice of public hearing.

SUMMARY: This document announces a public hearing to receive information and views on the Notice of Proposed Rulemaking (NPRM) entitled "National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table."

DATES: The public hearing will be held on December 6, 2001, from 10 a.m. to 12 p.m.

ADDRESSES: The public hearing will be held in Conference Room C in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, at (301) 443-6593.

SUPPLEMENTARY INFORMATION: The Secretary has made findings as to a condition that can reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus. Based on these findings, the Secretary proposes to amend the Vaccine Injury Table (Table) by adding to the Table vaccines containing live, oral, rhesus-based rotavirus as a distinct category, with intussusception listed as a covered Table injury. This proposal is based

upon the recommendation by the Centers for Disease Control and Prevention (CDC) that Rotashield, the only U.S.-licensed rotavirus vaccine, no longer be administered to infants in the United States based on review of data indicating a strong association between Rotashield and intussusception in the 1 to 2 weeks following vaccination.

The Secretary further proposes the following amendments: (1) Removing residual seizure disorder from the Table's Qualifications and Aids to Interpretation; (2) removing hemophilus influenzae type b polysaccharide (unconjugated) vaccines from the Table; (3) removing early onset Hib disease from the Table's Qualifications and Aids to Interpretation; and (4) adding pneumococcal conjugate vaccines to the Table with no condition specified. This latter item is based upon the CDC's recent recommendation of this vaccine for routine administration to children, as well as the enactment of the excise tax for this category of vaccines.

These proposed changes would have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the amendments to the existing regulations become effective.

The NPRM was published in the **Federal Register**, July 13, 2001; Vol. 66, No. 135, Pages 36735-36739. The public comment period closes January 9, 2002.

A public hearing will be held during the 180-day public comment period. This hearing is to provide an open forum for the presentation of information and views concerning all aspects of the NPRM by interested persons.

In preparing a final regulation, the Secretary will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the NPRM. Individuals or representatives of interested organizations are invited to participate in the public hearing in accord with the schedule and procedures set forth below.

The hearing will be held on December 6, 2001, beginning at 10 a.m., in Conference Room C in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, 20857. Upon entering the Parklawn Building, persons who wish to attend the hearing will be required to call Ms. Emma Boyd at (301) 443-6593 to be escorted to Conference Room C.

The presiding officer representing the Secretary, HHS will be Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, Office of Special Programs (OSP), Health Resources and Services Administration.

Persons who wish to participate are requested to file a notice of participation with the Department of Health and Human Services (HHS) on or before November 16, 2001. The notice should be mailed to Division of Vaccine Injury, OPS, Rm 8A-46, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, 20857. To ensure timely handling any outer envelope should be clearly marked "NPRM Hearing." The notice of participation should contain the interested person's name, address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested parties attending the hearing who did not submit a notice participation in advance will be allowed to make an oral presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, at (301) 443-6593 no later than November 16, 2001. Those persons who give oral notice of participation should also submit written notice containing the information described above to HHS by the close of business November 19, 2001.

After reviewing the notices of participation and accompanying information, HHS will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

Written comments and transcript of the hearing will be made available for public inspection as soon as they have been prepared, on weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m. at the Division of Vaccine Injury Compensation, Room 8A-46, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: October 29, 2001.

Elizabeth M. Duke,

Acting Administrator.

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