Dated: February 10, 2005.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. 05–3221 Filed 2–17–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0057]

Reviewer Guidance on Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a reviewer guidance entitled ''Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review.'' The guidance is intended to provide an annotated outline of the safety component of a clinical review of a new drug or biologic product application and guidance on how to conduct and organize the safety review. The guidance is also intended to provide standardization and consistency in the format, content, and quality of safety reviews. This reviewer guidance has been developed as part of the agency's good review practices initiative.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Robert Temple, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

SUPPLEMENTARY INFORMATION: This good review practice (GRP) guidance is intended to assist reviewers conducting clinical safety reviews as part of the new drug application (NDA) and biologics license application (BLA) review process. The guidance provides standardization and consistency in the format and content of safety reviews and will help ensure that critical presentations and analyses are not inadvertently omitted. The standardized structure of this guidance will enable subsequent reviewers and other readers to readily locate specific safety information. This guidance is entirely compatible with the clinical review template, which has been developed in the Center for Drug Evaluation and Research for use by application reviewers. The guidance is structured as an annotated outline to corrolate exactly with the section headings of the review template, providing the pertinent guidance under each heading. The commentary and suggestions under each section of the guidance, together with appended examples, provide suggested analyses, methods of presentations, and discussion of special cases and potential difficulties.

In 1996, FDA announced the availability of the draft version of this guidance. A number of comments were received, and the agency considered them carefully as it finalized the guidance. The changes that were made to the guidance were intended primarily to make it consistent with the template reviewers are using to evaluate marketing applications. Some minor clarifying changes also were made.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3181 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

New Methodology and Increase in Low Income Levels for Various Health Professions and Nursing Training and Assistance Programs

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: HRSA uses ''low-income'' levels to determine whether an individual is from an economically disadvantaged background in making eligibility and funding determinations for participants in various health professions and nursing grant and cooperative agreement programs authorized by Titles III, VII and VIII of the Public Health Service (PHS) Act. In the past, an individual's economically disadvantaged background status, as a basis for participation in certain programs, was based on the income level of the individual's parents. However, many potential program participants are well above the age of majority. Accordingly, questions have been raised by potential program participants and program officials regarding the feasibility and fairness in determining economically disadvantaged status based solely on the parent's income. This notice updates the low-income levels published by HRSA on August 5, 2003 (68 FR 46199–46200), and changes the methodology used to determine low income for use in these programs beginning in Fiscal Year (FY) 2005.

SUPPLEMENTARY INFORMATION: HRSA publishes low-income levels of families (68 FR 46199–46200, 8/5/03) for the use of various health professions training and assistance programs funded under Titles III, VII, and VIII of the PHS Act in making eligibility and funding determinations for participants in the programs. HRSA establishes these low-income levels based on the poverty guidelines that HHS publishes annually in the **Federal Register** (68 FR 7336, 2/13/2004). HHS determines the poverty guidelines based on the poverty

thresholds established by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index.

For FY 2005, HRSA has determined that:

- ''Low-income level'' as applied to a family is one with an annual income that is below 200 percent of HHS's poverty guidelines, as indicated in the table below, and
- A family is a group of two or more individuals related by birth, marriage, or adoption who live together or an individual who is not living with any relatives.

FY 2005 LOW INCOME LEVELS

Persons in family [1]	Income level [2]
1	$18,620
2	24,980
3	31,340
4	37,700
5	44,060
6	50,420
7	56,780
8	63,140

[1] Includes only dependents reported on Federal Income tax forms for calendar year 2003.
[2] Adjusted gross income for calendar year 2003.

New Methodology: Beginning in FY 2005, various programs in HRSA will use a new methodology in the application of low-income levels. Depending on the legislative intent of the program, the programmatic purpose of the low income level, as well as the age and circumstances of the average participant, each program will either apply the low-income levels to the family of the individual participant or to the family of the parents of the individual participant. Each program will announce the rationale and choice of methodology for determining low income levels in their program guidance.

Dated: February 11, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–3175 Filed 2–17–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Acting Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on April 1, 2004, through June 30, 2004.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Acting Director, Division of Vaccine Injury Compensation Program, Healthcare Systems Bureau, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Jennifer and Mark Chung on behalf of Gabrielle Chung
Houston, Texas