Dated: February 10, 2005.

Jeffrey Shuren,

Associate Commissioner for Policy.

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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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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.

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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