The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic.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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information mentioned in the guidance regarding the submission of manufacturer's information in an IND was approved under OMB control number 0910–0014.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3106 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0049]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is required, under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), to report annually in the **Federal Register** on the status of postmarketing study commitments made by sponsors of approved drug and biological products. This is the agency's report on the status of the studies sponsors have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research (HFD–20), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–3937; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

Section 130(a) of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies (section 506B of the act (21 U.S.C. 356b)) for human drug and biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study commitment that an applicant has been required or has agreed to conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study commitment. This report must also include reasons, if any, for failure to complete the commitment.

In the **Federal Register** of December 1, 1999 (64 FR 67207), FDA published a proposed rule providing a framework for the content and format of the annual progress report. The proposed rule also clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The final rule, published in the **Federal Register** of October 30, 2000 (65 FR 64607), modified annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). These regulations became effective on April 30, 2001. The regulations apply only to human drug and biological products. They do not apply to animal drug or to biological products that also meet the definition of a medical device.

Sections 314.81(b)(2)(vii) and 601.70 apply to postmarketing commitments made on or before enactment of the Modernization Act (November 21, 1997) as well as those made after that date. Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study that is required by FDA (e.g., accelerated approval clinical benefit studies) or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of other types of postmarketing commitments (e.g., those concerning chemistry, manufacturing, production controls, and studies conducted on an applicant's own initiative) are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70, and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii).

According to the regulations, once a postmarketing study commitment has been made, an applicant must report on the progress of the commitment on the anniversary of the product's approval until the postmarketing study commitment is completed or terminated, and FDA determines that the postmarketing study commitment has been fulfilled or that the postmarketing study commitment is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the postmarketing study commitment, a schedule for completing the study commitment, and a characterization of the current status of the study commitment. The report must also provide an explanation of the postmarketing study commitment's status by describing briefly the postmarketing study commitment's progress. A postmarketing study commitment schedule is expected to

include the actual or projected dates for the following items: (1) Submission of the study protocol to FDA; (2) completion of patient accrual or initiation of an animal study; (3) completion of the study; and (4) submission of the final study report to FDA. The postmarketing study commitment status must be described in the annual report according to the following definitions:

- Pending: The study has not been initiated, but does not meet the criterion for delayed;
- Ongoing: The study is proceeding according to or ahead of the original schedule;
- Delayed: The study is behind the original schedule;
- Terminated: The study was ended before completion, but a final study report has not been submitted to FDA; or
- Submitted: The study has been completed or terminated, and a final study report has been submitted to FDA.

Databases containing information on postmarketing study commitments are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Information in this report covers any postmarketing study commitment that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including those required (e.g., to demonstrate clinical benefit of a product following accelerated approval) and those agreed to with the applicant. Information summarized in this report includes the following items: (1) The number of applicants with open (uncompleted) postmarketing commitments; (2) the number of open postmarketing commitments; (3) the status of open postmarketing commitments as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports; (4) the status of concluded postmarketing studies as determined by FDA; and (5) the number of applications with open postmarketing commitments for which sponsors did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about postmarketing study commitments made by sponsors to CDER and CBER are provided on FDA's Web site at *http://www.fda.gov/cder*. Like this notice, the site does not list postmarketing study commitments containing proprietary information. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. The numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site. This notice incorporates totals for all postmarketing study commitments in FDA databases, including those undergoing review for accuracy. The report in this notice is updated annually while the Web site is updated quarterly (in April, July, October, and January).

II. Summary of Information From Postmarketing Study Progress Reports

This report summarizes the status of postmarketing commitments as of September 30, 2004. If a commitment did not have a schedule or a postmarketing progress report was not received, the commitment is categorized according to the most recent information available to the agency.

Data in table 1 of this document are numerical summaries generated from FDA databases. The data are broken out according to application type (NDAs/ANDAs or BLAs).

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2004)

	NDAs/ANDAs (% of Total)	BLAs[1] (% of Total)
Applicants with Open Postmarketing Commitments	54	46
Number of Open Postmarketing Commitments	1,191	288
Status of Open Postmarketing Commitments		
• Pending	812 (68%)	69 (24%)
• Ongoing	219 (18%)	114 (40%)
• Delayed	15 (1%)	37 (13%)
• Terminated	2 (<1%)	1 (<1%)
• Submitted	143 (12%)	67 (23%)
Concluded Studies (October 1, 2003, through September 30, 2004)	157	62
• Commitment Met	114 (73%)	45 (73%)
• Commitment Not Met	0	0
• Study No Longer Needed or Feasible	43 (27%)	17 (27%)
Applications with Open Postmarketing Commitments with Annual Reports Due but Not Submitted within 60 Days of the Anniversary Date of U.S. Approval	18 (16%)	51 (66%)

[1] On October 1, 2003, FDA completed a consolidation of certain products formerly regulated by CBER into CDER. The previous association of BLA reviews only with CBER is no longer valid; BLAs are now received by both CBER and CDER. Fiscal year statistics for CDER BLA postmarketing study commitments will continue to be counted under BLA totals in this table.

Dated: February 10, 2005.

Jeffrey Shuren,

Associate Commissioner for Policy.

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

BILLING CODE 4160–01–S

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