

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****[Docket No. 01D-0488]****Draft Guidance for Industry on Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling." The draft guidance is intended for sponsors planning to conduct food-effect bioavailability (BA) and fed bioequivalence (BE) studies for oral immediate-release and modified-release dosage forms as part of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements to these applications. The draft guidance provides recommendations for study design, data analysis, and product labeling, and also indicates when food-effect BA and fed BE studies should be performed.

**DATES:** Submit written or electronic comments on the draft guidance by January 28, 2002. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:**

Lawrence J. Lesko, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5690.

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling." This draft guidance is a revision of an October 1997 draft guidance entitled "Food-Effect Bioavailability and Bioequivalence Studies."

Food can delay gastric emptying, stimulate bile flow, change gastrointestinal (GI) pH, and increase splanchnic blood flow, thereby altering the BA of a drug product. Food can also change luminal metabolism of a drug substance and can physically or chemically interact with a dosage form or a drug substance to alter BA. Changes in BA can sometimes call for dosage adjustments or specific dosing instructions in relation to administration with meals. The physiological changes incurred due to food intake can influence the demonstration of BE between test and reference products.

Several study design variables may have an impact on the outcome of a food-effect BA or fed BE study. This draft guidance provides general information on study design and data analysis to assess the magnitude of food impact on the BA and BE of a drug product and indicates how this information can be appropriately addressed in the labeling. In addition, the draft guidance makes recommendations on when food-effect BA and fed BE should be performed.

This 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 food-effect bioavailability and fed bioequivalence studies. 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 statutes and regulations.

**II. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any 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 draft guidance and received comments are available for public examination in the Dockets

Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

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

Dated: November 15, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Disadvantaged Assistance Tracking and Outcome Report (OMB No. 0915-0233)—Revision**

The Health Careers Opportunity Program (HCOP) and the Centers of Excellence (COE) Program (sections 740 and 739 of the Public Health Service (PHS) Act, respectively) provide opportunities for under-represented

minorities and disadvantaged individuals to enter and graduate from health professions schools. The Disadvantaged Assistance Tracking and Outcome Report (DATOR), is used to track program participants throughout the health professions pipeline into the health care workforce. This request includes minor revisions to the previously approved data collection instrument that will address a number of data collection, data entry, as well as analytical problems encountered by the respondents.

The DATOR, to be completed annually by HCOP AND COE grantees,

includes basic data on students participants (name, social security number, gender, race/ethnicity; targeted health professions, their status in the educational pipeline from pre-professional through professional training; financial assistance received through the grants funded under sections 739 and 740 of the PHS Act in the form of stipends, fellowships or per diem; and their employment or practice setting following their entry into the health care work force).

The proposed reporting instrument is not expected to add significantly to the grantees reporting burden. This

reporting instrument complements the grantees internal automated reporting mechanisms of using name and social security number in tracking students. The reporting burden includes the total time, effort, and financial resources expended to maintain, retain and provide the information including: (1) Reviewing instructions; (2) downloading and utilizing technology for the purposes of collecting, validating, and processing the data; and (3) transmitting electronically, or otherwise disclosing the information. Estimates of annualized burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Dator .....	150	1	5.5	825

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 20, 2001.

**James J. Corrigan,**

*Associate Administrator for Management and Program Support.*

[FR Doc. 01-29513 Filed 11-27-01; 8:45 am]

**BILLING CODE 4165-15-P**

## 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 Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A-46, 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 after 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 July 5, 2001, through September 28, 2001.

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 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