

A panel of at least three reviewers (primarily experts from outside the Federal government) will use the evaluation criteria described in this announcement to evaluate each application. The reviewers will determine the strengths and weaknesses of each application, provide comments about the strengths and weaknesses and give each application a numerical score.

The results of the competitive review are a primary factor in making funding decisions. In addition, Federal staff conducts administrative reviews of the applications and, in light of the results of the competitive review, will recommend applications for funding to the ACYF Commissioner. ACYF reserves the option of discussing applications with other funding sources when this is in the best interest of the Federal government. ACYF may also solicit and consider comments from ACF Regional Office staff in making funding decisions. ACYF may take into consideration the involvement (financial and/or programmatic) of the private sector, national, or State or community foundations; a favorable balance between Federal and non-Federal funds for the proposed project; or the potential for high benefit from low Federal investment. ACYF may elect not to fund any applicants having known management, fiscal, reporting, programmatic, or other problems which make it unlikely that they would be able to provide effective services or effectively complete the proposed activity.

With the results of the peer review and the information from Federal staff, the Commissioner of ACYF makes the final funding decisions. The Commissioner may give special consideration to applications proposing services of special interest to the Government and to achieve geographic distributions of grant awards. Applications of special interest may include, but are not limited to, applications focusing on underserved or inadequately served clients or service areas and programs addressing diverse ethnic populations.

Available Funds. Applicants should note that grants to be awarded under this program announcement are subject to the availability of funds.

Approved but Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

3. Anticipated Announcement and Award Dates

Applications will be reviewed in the summer of 2005. Grant awards will have a start date no later than September 30, 2005.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental).

Direct federal grants, sub-award funds, or contracts under this program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this program. Regulations pertaining to the prohibition of Federal funds for inherently religious activities can be found on the HHS web site at <http://www.os.dhhs.gov/fbc/waisgate21.pdf>

Special Terms and Conditions

None.

3. Reporting Requirements

Program Progress Reports: Semi-annually.

Financial Reports: Semi-annually.

Grantees will be required to submit program progress and financial reports (SF-269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

Performance Indicator Data, Programmatic Reports and Financial Reports are required semi-annually. All required reports will be submitted in a timely manner, in recommended formats (to be provided), and the final

report will also be submitted on disk or electronically using a standard word-processing program.

Within 90 days of project end date, the applicant will submit a copy of the final report and any program products to the National Clearinghouse on Child Abuse and Neglect Information, 330 C Street, SW., Washington, DC 20447. This is in addition to the standard requirement that the final program and evaluation report must also be submitted to the Grants Management Specialist and the Federal Project Officer.

II. Agency Contacts

Program Office Contact: Jan Shafer, Administration for Children and Families, Children's Bureau, 330 C Street, SW., Washington, DC 20447, phone: 202-205-8172, e-mail: jshafer@acf.hhs.gov.

Grants Management Office Contact: Peter Thompson, Grants Officer, Administration for Children and Families, Children's Bureau, 330 C Street, SW. Room 2070, Washington, DC 20447, phone: 202-401-4608, e-mail: pthompson@acf.hhs.gov.

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: <http://www.Grants.gov>. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: <http://www.acf.hhs.gov/grants/index.html>.

Additional information about this program and its purpose can be located on the following Web sites: <http://www.acf.hhs.gov/programs/cb/>.

For general questions regarding this announcement please contact: ACYF Operations Center, The Dixon Group ATTN: Children's Bureau, 118 Q Street, NE., Washington DC 20002-2132, Telephone: 866-796-1591.

Applicants will not be sent acknowledgements of received applications.

Dated: May 25, 2005.

Susan Orr,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05-11197 Filed 6-3-05; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 2005D-0203]

Draft Guidance for Industry on Safety Testing of Drug Metabolites; 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 "Safety Testing of Drug Metabolites." This draft guidance provides recommendations on the safety assessment of unique or major human metabolites of small molecule (nonbiologic) therapeutic products under development. This draft guidance is intended to serve as a resource for general testing considerations as well as provide recommendations on the timing of these studies in relation to the clinical development.

DATES: Submit written or electronic comments on the draft guidance by August 5, 2005. 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 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:

Aisar Atrakchi, Center for Drug Evaluation and Research (HFD-120), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301-594-2850.

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Safety Testing of Drug Metabolites." There are quantitative and qualitative differences in metabolic profiles across species. These differences become

important when exposure parameters of a drug in a nonclinical species are used to assess safety in humans during risk assessment. In the past, contribution of metabolites to the overall toxicological potential of the parent drug was generally unknown or not considered; analytical technologies to identify and measure metabolites have only become available over the past decade.

Although in general there is adequate correlation in metabolic profiles between humans and those obtained in standard nonclinical safety studies, there are, however, cases when these studies do not adequately evaluate clinically relevant and/or biologically active metabolites. This may be due to such metabolites being unique to humans or present at very low levels in the animal species used in the standard toxicity studies. As a result, FDA has developed a draft guidance to provide recommendations on the safety assessment of unique or major human metabolites of small molecule (nonbiologic) therapeutic products. These recommendations should help applicants conduct adequate safety assessments of metabolites.

This draft guidance provides general testing considerations for unique or major drug metabolites including study design, identification of metabolites, structure activity relationship, and types of nonclinical studies needed to assess metabolite toxicity. It also addresses the timing of these studies in relation to the clinical development.

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 safety testing of drug metabolites. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the document. 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management 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: May 27, 2005.

Jeffrey Shuren,*Assistant Commissioner for Policy.*

[FR Doc. 05-11205 Filed 6-3-05; 8:45 am]

BILLING CODE 4160-01-S**DEPARTMENT OF HOMELAND SECURITY****Coast Guard**

[USCG-2005-21322]

Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Number: 1625-0015**AGENCY:** Coast Guard, DHS.**ACTION:** Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of one Information Collection Request (ICR). The ICR is for 1625-0015, Bridge Permit Application Guide. Before submitting the ICR to OMB, the Coast Guard is inviting comments on it as described below.

DATES: Comments must reach the Coast Guard on or before August 5, 2005.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG-2005-21322] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part