Service Act (the PHS Act) (42 U.S.C. 262). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the act and the PHS Act. The information, which is usually submitted as part of a new drug application or biologics license application or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved by OMB under OMB control number 0910–0001). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well established, low risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					4,000

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9159 Filed 4–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the World Health Organization International Programme on Chemical Safety

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement (U01), a new Sole Source, Competitive Continuation in fiscal year 2008 to the World Health Organization (WHO) International Programme on Chemical Safety (IPCS). This Request for Applications (RFA) is supported by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). This program is described in the Catalog of Federal Domestic Assistance No. 93.103 under RFA Number: RFA–FD–08–002. A copy of the complete RFA can also be viewed on CFSAN's Web site (*http://www.cfsan.fda.gov*) and on CVM's Web site (*http://www.fda.gov/cvm*).

This RFA will strengthen and allow WHO to continue their work in important international risk assessment and standard setting activities for food ingredients, contaminants, and veterinary drug residues in food. WHO/IPCS is an umbrella organization that provides for timely international collaboration on multinational cooperative activities. Various programs under the WHO/IPCS, such as the Joint Food and Agriculture (FAO)/WHO Expert Committee on Food Additives (JECFA), significantly contribute to internationally-recognized, science-based risk assessments of food additives, contaminants, and residues of veterinary drugs in foods. The Codex Alimentarius Commission (CAC) relies on JECFA's scientific advice when establishing international standards for foods. The WHO/IPCS also supports

FAO/WHO Expert Consultations on risk assessments for emerging or cross-cutting issues (e.g., non-dioxin-like polychlorinated biphenyls (PCBs), allergenicity of foods derived from biotechnology, risk-benefit assessment of the use of active chlorine species in food processing). The evaluations that are produced by these Expert Consultations provide a sound scientific basis for Codex's standard-setting activities that contribute to improved public health and food safety worldwide.

The following activities are to be supported by this cooperative agreement:

1. Schedule, plan, and conduct appropriate work groups, consultations, and committee meetings, which have emphasis on, but are not limited to, food additives, contaminants, and residues of veterinary drugs in food.

2. Identify advisers, and prepare written working papers summarizing the data on substances under consideration.

3. Prepare written working papers and technical documents for the JECFA, and for the FAO/WHO Expert Consultations related to food additives, contaminants, and residues of veterinary drugs in food.

II. Award Information

A. Mechanism of Support

This funding opportunity will use a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator.

Receipt Date: Within 45 days after the publication of this announcement in the **Federal Register**.

B. Funds Available

The estimated amount of funds available for support of this cooperative agreement is $120,000 (direct and indirect costs) for fiscal year 2008. It is anticipated that an additional 4 years of support will be available at $90,000 per year, depending on annual appropriations and successful performance.

This award will be funded based on the quality of the application received and is subject to the availability of Federal funds to support the project. In addition, if a cooperative agreement is awarded, the grantee will be informed of any additional documentation that should be submitted to the FDA.

III. Eligibility Information

Eligible Institutions

Competition is limited to the WHO/IPCS because, as the parent organization of the JECFA, it is solely responsible for providing scientific advice, including risk assessments, to the CAC on matters related to food additives, contaminants, and residues of veterinary drugs in food. Thus, the programs under the IPCS are unique. It is essential that the WHO/IPCS be able to provide science-based risk assessments that are of the highest integrity, as these assessments form the basis of international standards that both protect public health and promote fair trade practices. Awarding this cooperative agreement to the WHO/IPCS will ensure that JECFA's risk assessments are science-based, will enhance the safe use of food additives, will ensure that residues of veterinary drugs in imported foods are safe, and will help to ensure that food sold in the United States is safe.

IV. Application and Submission Information

The PHS 398 application instructions are available at *http://grants.nih.gov/grants/funding/phs398/phs398.html* in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact Grants Info at 301–435–0714, e-mail: *GrantsInfo@nih.gov*.

Telecommunications for the hearing impaired: TTY 301–451–0088.

A. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a Dun & Bradstreet Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling 866–705–5711 or through the Web site at *http://www.dnb.com/us/*. The DUNS number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on lines 1 and 2 of the face page of the application form and the YES box must be checked.

Required 398 Application Components must be submitted in Non Modular format as follows:

Form Page 1: Face Page; Form Page 2: Description, Performance Sites, Key Personnel, Other Significant Contributors; Form Page 3: Table of Contents; Form Page 4: Detailed Budget for Initial Budget Period: Form Page 5: Budget for Entire Proposed Period of Support: Biographical Sketch Format Page; Resources Format Page; Checklist Form Page: Personal Data Form Page; Other Support Format Page; Personnel Report Format Page.

B. Sending an Application to FDA

The application must be prepared using the forms found in the PHS 398 instructions for preparing a research grant application. Applications will be accepted in hard copy or electronically at *http://www.grants.gov*. A signed hard copy original application and three signed photocopies should be sent to:

Food and Drug Administration/OAGS/GAAT/Gladys M. Bohler, 5630 Fishers Lane, rm. 2105, HFA–500, Rockville, MD 20857 (U.S. Postal Service Express or regular mail).

FDA will also accept the application for this program electronically via *http://www.grants.gov*. The applicant is encouraged to apply electronically by visiting the Web site *http://www.grants.gov* and following instructions under ''Apply for Grants.'' The required application, SF 424 (R&R) can be completed and submitted online. The package should be labeled, ''Response to RFA FD–08–002.'' If you experience technical difficulties with your online submission you should contact Gladys M. Bohler by telephone at 301–827–7168 or by e-mail at *gladys.melendez-bohler@fda.hhs.gov*

Information about submitting an application electronically can be found on the *http://www.grants.gov* Web site.

PHS 398 Research Plan Component Sections via Grants.gov

Items 2 through 5 of the PHS 398 Research Plan component are limited to 25 pages. While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to FDA in PDF format, filenames must be included with no spaces or special characters, and a pdf extension must be used.

In order to apply electronically the applicant must have a DUNS number and register in the central contractor registration (CCR) database.

C. Intergovernmental Review

This initiative is not subject to intergovernmental review under the terms of Executive Order 12372.

D. Other Submission Requirements and Information

Several additional separate actions are required before an applicant institution/organization can submit an application.

Organizational DUNS—As of October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number applicants should go to *http://www.grants.gov/RequestaDUNS*.

Central Contractor Registration—Applicants must register with the CCR database. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for completing a registration is at *http://www.ccr.gov*. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online preregistration as well as steps to walk you through the registration process. You must have a DUNS number to begin your registration. For foreign entities the Web site is *http://www.grants.gov/RequestaDUNS.gov*. In order to access Grants.gov an applicant will be required to register with the Credential Provider. Information about this is available at *https://apply.grants.gov/OrcRegister*.

A copy of the complete RFA can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at *http://www.cfsan.fda.gov/list.html*.

Foreign Applications (Non-domestic (non-U.S.) Entity)

- Indicate how the proposed project has specific relevance to the mission and objectives of FDA and has the potential for significantly advancing sciences in the United States.
- Research grant applications from foreign or international organizations may not be funded unless approved by the National Cancer Institute National Advisory Board.

IV. Agency Contacts

A. Scientific/Research Contacts

For issues regarding the programmatic aspects of this document, contact Susan E. Carberry at 301–436–1269 or by e-mail: *susan.carberry@fda.hhs.gov*.

B. Financial or Grants Management Contacts

For issues regarding the administrative and financial management aspects, contact Gladys Melendez-Bohler at 301–827–7168 or by e-mail: *gladys.melendez-bohler@fda.hhs.gov*.

Dated: April 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9251 Filed 4–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0233]

Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated April 2008. This draft guidance is intended for establishments that collect Whole Blood and blood components intended for transfusion and establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The document provides recommendations for testing of donations of Whole Blood and blood components and HCT/P donor specimens for West Nile Virus (WNV) using an FDA-licensed donor screening assay. FDA believes that the use of a licensed nucleic acid test (NAT) will reduce the risk of transmission of WNV, and therefore recommend use of a licensed NAT to screen donors of Whole Blood and blood components intended for transfusion and for testing donors of HCT/Ps for infection with WNV. FDA recommends the use of licensed NAT testing for WNV within 6 months after a final guidance is issued.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 28, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated April 2008. This draft guidance is intended for establishments that collect Whole Blood and blood components intended for transfusion and establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products HCT/Ps. The document provides recommendations for testing of donations of Whole Blood and blood components and HCT/P donor specimens for WNV using an FDA-licensed donor screening assay. FDA believes that the use of a licensed NAT will reduce the risk of transmission of WNV, and therefore recommend use of a licensed NAT to screen donors of Whole Blood and blood components intended for transfusion and for testing donors of HCT/Ps for infection with WNV. FDA recommends the use of licensed NAT testing for WNV within 6 months after a final guidance is issued.