If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Brenda Hayes, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00006, Centers for Disease Control and Prevention (CDC), Grants Management Office Room 3000, Attn: Colgate Building, 2920 Brandywine Rd., Mailstop E–15, Atlanta, GA 30341, telephone (770) 488–2741, Email address bkh4@cdc.gov

For program technical assistance, contact: Jeff Efird, MPA, Deputy Chief, Epidemiology Branch, Division of HIV/AIDS Prevention, Surveillance & Epidemiology, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–45, Atlanta, Georgia 30333, Telephone (404) 639–6130, E-mail jle1@cdc.gov

Dated: July 3, 2000.

Ron Van Duyne,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–17294 Filed 7–7–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grant for Research on the Impact of Laws and Policies on Public Health, Program Announcement #00051

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grant for Research on the Impact of Laws and Policies on Public Health, Program Announcement #00051.

Times and Dates: 7 p.m.–7:30 p.m., August 1, 2000 (Open); 7:30 p.m.–9:30 p.m., August 1, 2000 (Closed); 8 a.m.–4:30 p.m., August 2, 2000 (Closed).

Place: Airport Crowne Plaza Hotel, Virginia Avenue, Atlanta, Georgia 30344. Telephone 404/768–6660.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #00051.

Contact Person for More Information: Richard A. Goodman, M.D., M.P.H., Senior Advisor for Science and Policy, Centers for Disease Control and Prevention, 1600 Clifton Road m/s D03, Atlanta, Georgia 30333. Telephone 404/639–7400, email rag4@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 3, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

[FR Doc. 00–17293 Filed 7–7–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety Research: Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of research funds for fiscal year (FY) 2000 to support research in the following areas of produce safety, egg safety, development of extraction procedures of foodborne viruses from foods to enhance detection, and food service, transportation, and consumer practices. Approximately $600,000 will be available in FY 2000. FDA anticipates making three to four awards at $100,000 to $200,000 (direct and indirect costs) per award per year. Support of these agreements may be up to 3 years. The number of agreements funded will depend on the quality of the applications received and the availability of Federal funds to support the project. After the first year, additional years of noncompetitive support are predicated upon performance and the availability of Federal fiscal year funds.

DATES: Submit applications by August 24, 2000.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Maura C. Stephanos, Grants Management Specialist, Grants Management Office (HFA–520), Division of Contracts and Procurement Management, Office of the Director, Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, FAX 301–827–7106, e-mail: mstepha1@oc.fda.gov. (Applications hand-carried or commercially delivered should be addressed to rm. 2129, 5630 Fishers Lane, Rockville, MD 20852).

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Maura C. Stephanos (address above).

Regarding the programmatic aspects of this notice: Marianna D. Miliotis, Food Safety Initiative Extramural Research Coordinator, Office of Plants, Dairy Foods, and Beverages (HFS–327), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4824, e-mail: mmilioti@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: FDA will support the research studies covered by this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national activity to reduce morbidity and mortality and to improve the quality of life. Applicants may obtain a hard copy of the ''Healthy People 2010'' objectives, vols. I and II, conference edition (B0074) for $22 per set, by writing to the Office of Disease Prevention and Health Promotion (ODPHP) Communication Support Center (Center), P.O. Box 37366, Washington, DC 20013–7366. Each of the 28 chapters of ''Healthy People 2010'' is priced at $2 per copy. Telephone orders can be placed at the Center on 301–468–5690. The Center also sells the complete conference edition in CD–ROM format (B0071) for $5. This publication is available as well on the Internet at www.health.gov/healthypeople. Internet viewers should proceed to ''Publications.''

I. Background

FDA is mandated by the President's Food Safety Initiative (FSI) to reduce the incidence of foodborne illness to the greatest extent feasible. Research in food safety seeks to reduce the incidence of foodborne illness by improving our ability to detect and enumerate pathogens in the food supply and to find new ways to control them. In FY 1998, the Center for Food Safety and Applied Nutrition (CFSAN) obligated $2 million to support eight multiyear cooperative agreements. This extramural program inaugurated a novel collaborative research effort between CFSAN and academic scientists, and leveraged expertise, not found within FDA, to accelerate ongoing research. Collaborations such as these provide information critical to food safety guidance and policymaking, and stimulate fruitful interactions between FDA scientists and those within the greater research community.

In continuation of this effort, CFSAN/FSI will provide FY 2000 funds to be used for research to help ensure produce and egg safety, develop extraction methods for viruses in foods, and determine food storage practices from processing to consumption.

II. Research Goals and Objectives

The goals and objectives of this program will be to: (1) Ensure produce safety by standardizing inoculation methods for determining the efficacy of antimicrobial chemicals or technologies or for validation of Hazard Analysis Critical Control Point (HACCP) systems, particularly in fresh or minimally processed produce; (2) evaluate surrogate microorganisms for use in HACCP validation; (3) ensure egg safety by developing improved sampling and detection methods for detection of low-levels of and enumeration of *Salmonella* Enteritidis (*S.* Enteritidis) in eggs; (4) develop extraction and processing methods suitable for reverse-transcription polymerase chain reaction (RT–PCR) based identification/detection of foodborne viruses; and (5) obtain information to support the science behind the U.S. Public Health Service Food Code, which provides guidance to the retail and food service industry, as well as information to support guidance to the consumer.

Projects that fulfill any one of the following specific objectives will be considered for funding. Applications may address only one project objective; however, applicants may submit more than one application for any of the project objectives. The project objectives are listed below in order of priority.

A. Project Objective 1 (Priority #1)

The first priority is to develop extraction and processing methods suitable for RT–PCR based identification/detection of foodborne viruses, such as Hepatitis A virus (HAV) and Norwalk virus. Commodities of interest include raw or minimally processed foods, such as strawberries, raspberries, grapes, tomatoes, and seafood. Extraction and sample processing methods must not interfere or inhibit RT–PCR based detection of the virus(es) and be applicable for analysis of large or bulk quantities of foods. The entire methodology, from extraction to detection, must include appropriate and exhaustive positive and negative controls to ensure validity of the extraction, processing, and detection (RT–PCR based) methods. These controls must also include those designed to confirm or exclude the absence of viral particle/genome contamination among and/or between food samples and reagents.

B. Project Objective 2 (Priority #2)

The second priority is to determine the effect of different inoculation procedures (e.g. dipping, spraying, spotting) on the efficacy of disinfectants and intervention technologies to remove or inactivate microorganisms, and determine how procedures perform under practical conditions. Ensuring produce that is safe for the consumer to eat is a major priority. Research needed to address this issue includes standard inoculation methods for performing challenge studies. FDA has continually sponsored research in intervention strategies to mitigate the risk of foodborne illness and reviewed applications for new antimicrobial agents and intervention technologies. The initiative provides an opportunity to expand the range of research questions addressed by FDA in intervention strategies for standardization of inoculation procedures for testing efficacy of intervention strategies. Currently, challenge inoculation methods tend to allow limited times for attachment of cells to food surfaces (and often under unrealistic conditions). This makes interpretation of the results difficult. Published studies have also demonstrated problems with statistical reproducibility when the attachment period is lengthened. An ideal inoculation protocol would permit sufficient time for cell attachment under conditions simulating those encountered in food growing and processing environments, such as low nutrient levels and ambient temperatures. The protocol tests must include a comparison of application techniques including spot, spray, and dip inoculation methods.

C. Project Objective 3 (Priority #3)

To determine whether consumer and industry practices are sufficient to protect the consumer from foodborne illness, research is needed in the following areas:

(1) Examine acceptability of the U.S. Public Health Service Food Code's requirements for: (a) Four-hour holding limit for all foods at ambient temperature, (b) the appropriateness for cooling foods from 140 to 41 ½F in 6 hours, and (c) the potential impact for human health risks if hot foods are held at 130 ½F.

(2) Quantitatively describe whether cooking practices used in the home are sufficient to inactivate pathogenic bacteria, viruses, or parasites that may be present in specific foods.

(3) Explore consumer practices related to storage of selected food products, including when and where it is stored in the refrigerator, refrigerator temperatures, length of time refrigerated food is kept, and consumer knowledge and beliefs related to food safety and refrigeration.

D. Project Objective 4 (Priority #4)

To ensure that eggs are safe, there is a need to study egg safety, specifically sampling and detection methods for *S.* Enteritidis in eggs and layer flocks. Current egg sampling practices may fail to detect low levels of *S.* Enteritidis. Therefore, there is a need to:

(1) Develop improved sampling and detection methods to detect low-levels of, and more significantly enumerate, *S.* Enteritidis in eggs and layer flocks. The development of a sampling plan should be based on known incidence data to ensure that a negative test result from a sample, indicates with a high level of confidence that the organism is not present in the entire lot or shipment. The sampling plan should consider not only occurrence of *S.* Enteritidis, but also dispersion or distribution of this pathogen among groups of eggs, and should be statistically superior to present sampling and detection techniques.

(2) Develop better on-farm indicators for predicting whether eggs are contaminated with *S.* Enteritidis.

E. Project Objective 5 (Priority #5)

The fifth priority is to determine which microorganisms are most suitable for use as surrogates for foodborne pathogens and are appropriate for specific commodities in challenge

studies to validate microbial hazard reduction technologies. The experimental use of pathogenic microorganisms in food establishments or pilot plants is generally contraindicated, but it is necessary to perform challenge studies to validate microbial hazard reduction technologies. In order to overcome this problem, the comparison of surrogate microbes to pathogenic counterparts (bacteria, viruses, and parasites) is necessary. Surrogates that are appropriate for specific commodities should be proposed. They should exhibit similar growth and binding characteristics, on a target commodity, of the foodborne pathogen represented, and should exhibit equivalent resistance to common classes of disinfectants. Successful projects will recommend surrogates based on a range of comparative physiological, genetic, and kinetics studies.

III. Human Subject Protection and Informed Consent

A. Protection of Human Research Subjects

Some activities carried out by a recipient under this announcement may be governed by the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects (45 CFR part 46). These regulations require recipients to establish procedures for the protection of subjects involved in any research activities. Prior to funding and upon request of the Office for Protection from Research Risks (OPRR), prospective recipients must have on file with OPRR an assurance to comply with 45 CFR part 46. This assurance to comply is called an Assurance document. It includes the designated Institutional Review Board (IRB) for review and approval of procedures for carrying out any research activities occurring in conjunction with this award. If an applicable Assurance document for the applicant is not already on file with OPRR, a formal request for the required Assurance will be issued by OPRR at an appropriate point in the review process, prior to award, and examples of required materials will be supplied at that time. No applicant or performance site, without an approved and applicable Assurance on file with OPRR, may spend funds on human subject activities or accrue subjects. No performance site, even with an OPRR-approved and applicable Assurance, may proceed without approval by OPRR of an applicable Assurance for the recipients. Applicants may wish to contact OPRR by facsimile (301–402–0527) to obtain preliminary guidance on human subjects issues. When contacting OPRR, applicants should provide their institutional affiliation, geographic location, and all available Request for Applications (RFA) citation information.

Applicants are advised that the section on human subjects in the application kit entitled ''Section C. Specific Instructions—Forms, Item 4, Human Subjects,'' on pages 7 and 8 of the application kit, should be carefully reviewed for the certification of IRB approval requirements. Documentation of IRB approval for every participating center is required to be on file with the Grants Management Officer, FDA. The goal should be to include enough information on the protection of human subjects in a sufficiently clear fashion so reviewers will have adequate material to make a complete review. Those approved applicants who do not have a current Multiple Project Assurance with OPRR will be required to obtain a Single Project Assurance from OPRR prior to award.

B. Informed Consent

Consent and/or assent forms, and any additional information to be given to a subject, should accompany the grant application. Information that is given to the subject or the subject's representative must be in language that the subject or his or her representative can understand. No informed consent, whether oral or written, may include any language through which the subject or the subject's representative is made to waive any of the subject's legal rights, or by which the subject or representative releases or appears to release the investigator, the sponsor, or the institution or its agent from liability.

If a study involves both adults and children, separate consent forms should be provided for the adults and the parents or guardians of the children.

C. Elements of Informed Consent

The regulations on informed consent are set forth in 45 CFR 46.116 and 21 CFR 50.25. The basic elements of informed consent are as follows:

1. Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject.

• A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

• A description of any reasonably foreseeable risks or discomforts to the subject.

• A description of any benefits to the subject or to others which may reasonably be expected from the research.

• A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

• A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained, and that notes the possibility that FDA may inspect the records.

• For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

• An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject.

• A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject.

• A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

• Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

• Any costs to the subject that may result from participation in the research.

• The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

• A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

• The approximate number of subjects involved in the study.

• The informed consent requirements are not intended to preempt any

applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

• Nothing in the notice is intended to limit the authority of a physician to provide emergency medical care to the extent that a physician is permitted to do so under applicable Federal, State, or local law.

IV. Reporting Requirements

A Program Progress Report and a Financial Status Report (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer (address same as given above for Grants Management Specialist) within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR (SF–269) on time may be grounds for suspension or termination of the agreement. Progress reports will be required quarterly within 30 days following each fiscal year quarter (January 31, April 30, July 30, October 31), except that the fourth report will serve as the annual report and will be due 90 days after the budget expiration date. CFSAN program staff will advise the recipient of the suggested format for the Program Progress Report at the appropriate time. A final FSR (SF–269), Program Progress Report and Invention Statement, must be submitted within 90 days after the expiration of the project period, as noted on the Notice of Grant Award.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least quarterly by the Project Officer and the Project Advisory Group. Project monitoring may also be in the form of telephone conversations between the Project Officer/Grants Management Specialist and the Principal Investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be duly recorded in the official file and may be available to the recipient upon request.

V. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of cooperative agreements. These cooperative agreements will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program.

B. Eligibility

These cooperative agreements are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive awards.

C. Length of Support

The length of support will be for up to 3 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year, and/or (2) the availability of Federal FY funds.

VI. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have a substantive involvement in the programmatic activities of all the projects funded under this RFA. Substantive involvement includes but is not limited to the following:

1. FDA will provide guidance and direction with regard to the scientific approach and methodology that may be used by the investigator.

2. FDA will participate with the recipient in determining and executing any: (a) Methodological approaches to be used, (b) procedures and techniques to be performed, (c) sampling plans proposed, (d) interpretation of results, and (e) microorganisms and commodities to be used.

3. FDA will collaborate with the recipient and have final approval on the experimental protocols. This collaboration may include protocol design, data analysis, interpretation of findings, coauthorship of publications and the development and filing of patents.

VII. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. Applications will be considered nonresponsive if they are not in compliance with sections VII.B and VIII of this document. If applications are found to be nonresponsive to this announcement, they will be returned to the applicant without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers. Final funding decisions will be made by the Commissioner of FDA or his designee.

B. Review Criteria

The funding priority categories are as follows: Project Objective 1—first priority; Project Objective 2—second priority; Project Objective 3—third priority; Project Objective 4—fourth priority, and Project Objective 5—fifth priority.

Applicants must clearly state in their applications which of the above-established funding priority categories is relevant to their proposed project. Applications will be grouped, reviewed, and ranked within each funding priority category. Funding priority will start with the highest ranked applications under each of the five objectives, then the second highest, etc., until available funds have been exhausted. All applications will be evaluated by program and grants management staff for responsiveness. Applications considered nonresponsive will be returned to the applicant without being reviewed. Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their application. All questions of a technical or scientific nature must be directed to the CFSAN program staff, and all questions of an administrative or financial nature must be directed to the grants management staff (see the Information Contact section at the beginning of this document for addresses.) Applications will be reviewed and scored on the following criteria:

1. For Project Objective 3 only—Research should be proposed on commercial time/temperature practices, Food Code requirements, home cooking practices, or home refrigeration practices, that is within Project Objective 3 in Section II. Research Goals and Objectives of this document;

2. For Project Objective 4 only—Research should be proposed on sampling and detection of *S.* Enteritidis in eggs, or on farm indicators for predicting whether eggs are contaminated with *S.* Enteritidis, that is within Project Objective 4 in Section II. Research Goals and Objectives of this document;

3. For all Project Objectives—Whether the proposed study is within the budget,

and costs have been adequately justified and fully documented;

4. For all Project Objectives—Soundness of the rationale for the proposed study and appropriateness of the study design to address the objectives of the RFA;

5. For all Project Objectives—Availability and adequacy of laboratory facilities and equipment;

6. For all Project Objectives—Availability and adequacy of support services, e.g., biostatistical computer, data bases, etc., and;

7. For all Project Objectives—Research experience, training, and competence of the principal investigator and support staff.

VIII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98) or the original and two copies of PHS 5161 (Rev. 6/99) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura C. Stephanos (address above). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161. The application receipt date is August 24, 2000. No supplemental or addendum material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled: ''Response to RFA FDA CFSAN–00, Project Objective 1 (1–5).''

IX. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), NIH. Any application that is sent to NIH, that is then forwarded to FDA and not received in time for orderly processing, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet at http://www.nih.gov.grants/phs398/phs398.html; the forms can be found at http://www.nih.gov/grants/phs398/forms—toc.html. However, as noted above, applications are not to be mailed to NIH. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications. Applications must be submitted via mail delivery as stated above. FDA is unable to receive applications via the Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address.

The face page of the application should reflect the request for applications number RFA–FDA–CFSAN–00, Project Objective 1 (2, 3, 4, or 5).

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: June 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–17276 Filed 7–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Wireless Technology Research; Effects of Radiofrequency Energy on Micronucleus Formation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Radiofrequency Micronucleus Working Group. This is the initial meeting of a working group of national and international scientific experts convened to review the results of studies, previously conducted by Wireless Technology Research, L.L.C., on the effects of radiofrequency energy on micronucleus formation, and to recommend a statement of work for additional research. This meeting is being convened as the initial step in a Cooperative Research and Development Agreement (CRADA) between the Center for Devices and Radiological Health of FDA and the Cellular Telecommunications Industry Association (CTIA), consistent with Appendix A of the CRADA. The meeting will be open to the public.

Date and Time: The meeting will be held on August 1, 2000, 8:30 a.m. to 5 p.m., and on August 2, 2000, 8:30 a.m. to 11:30 a.m.

Location: 9200 Corporate Blvd., rm 020-B, Rockville, MD 20850.

Contact: Russell Owen, Center for Devices and Radiological Health, Food and Drug Administration (HFZ–114), 12709 Twinbrook Pkwy., Rockville, MD 20857, 301–443–7118, FAX 301–594–6775. Further information about the CRADA is available at http://www.fda.gov/cdrh/ocd/wlessphonecrada.html on the Internet.

Agenda: On August 1, 2000, the working group will hear presentations related to radiofrequency exposure systems and dosimetry and prior reports of micronucleus formation in cells exposed to radiofrequency. On August 2, 2000, the working group will discuss the types of studies needed to further investigate and refine prior reports of micronucleus formation caused by radiofrequency exposure.

Procedure: Interested persons may present data, information, or views on issues to be discussed by the working group. Written submissions may be made to the contact person by July 14, 2000. Oral presentations from the public will be scheduled on August 1, 2000,