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,

between approximately 3 p.m. and 5 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 14, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please contact Ms. Toni Fennell, 301–443–7118 at least 7 days in advance.

Dated: June 29, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–17277 Filed 7–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1350]

Draft Guidance for Industry on Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients; 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 ''Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients.'' FDA's Center for Drug Evaluation and Research is issuing this draft guidance for drug products in the combined oral contraceptives class. When finalized, the guidance should result in uniform labeling among combined oral contraceptive products. Uniform labeling is important to physicians and patients when they read and try to understand efficacy claims and safety risks associated with drug products in this class. In addition, this draft guidance is intended to provide sponsors of new combined oral contraceptive drug products with a labeling template.

DATES: Submit written comments on the draft guidance by September 8, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients.'' The draft guidance is intended to produce uniform labeling among combined oral contraceptive products. Uniform labeling is important to physicians and patients in understanding efficacy claims and safety risks associated with drug products in this class. The draft guidance, which outlines recommendations for the physician insert, also includes a labeling template for physician labeling and instructions for use that can be used for new drug applications and abbreviated new drug applications. Among the labeling recommendations is a black box warning explaining the increased risk of serious cardiovascular side effects associated with the concomitant use of cigarettes and combined oral contraceptives. Once the draft guidance is finalized, the recommended text should be included in all approved, pending, and future applications. This labeling guidance is intended to supersede the ''Labeling Guidance for Combination Oral Contraceptives, Physician and Patient Labeling,'' revised in August 1994.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on combined oral contraceptive labeling for healthcare providers and patients. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written 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.

Dated: June 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–17278 Filed 7–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Correction

AGENCY: Health Resources and Services Administration.

ACTION: Notice; correction.

SUMMARY: In the **Federal Register** notice of Monday, June 5, 2000, in FR Doc. 00–13951, on page 35657, beginning in the first column under grant category (2) ''Partnership for State Oral Health Leadership Cooperative Agreement (MCHB),'' reference is made to ''Funding Priorities and/or Preferences: A funding preference will be given to institutions of higher learning with extensive experience in early discharge research, linkage with the Secretary's Advisory Committee on Infant Mortality, and published research and recognition in the relevant field.'' This reference was erroneous and should be corrected to read: ''Funding Priorities and/or Preferences: None.''

FOR FURTHER INFORMATION CONTACT: David Heppel, M.D., Director, Division of Child, Adolescent, and Family Health, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone 1–301–443–2250.