

recommended for approval but not funded using FY 2004 funds will remain in competition for FY 2005 funds along with those applications received for the April 7, 2004, and October 6, 2004, due dates. Applications submitted for the first due date may be withdrawn and resubmitted for the second due date.

Grants will be awarded for \$150,000 or \$300,000 in direct costs a year, plus applicable indirect costs, for up to 3 years. Applications for the smaller grants (\$150,000) may be for phase 1, 2, or 3 studies. Study proposals for the larger grants (\$300,000) must be for studies continuing in phase 2 or phase 3 of investigation. Phase 1 studies include the initial introduction of an investigational new drug or device into humans, are usually conducted in healthy volunteer subjects, and are designed to determine the metabolic and pharmacological actions of the product in humans, the side effects including those associated with increasing drug doses and, if possible, to gain early evidence on effectiveness. Phase 2 studies include early controlled clinical studies conducted to evaluate the effectiveness of the product for a particular indication in patient's with the disease or condition and to determine the common short-term side effects and risks associated with it. Phase 3 studies gather more information about effectiveness and safety that is necessary to evaluate the overall risk-benefit ratio of the product and to provide an acceptable basis for product labeling. Budgets for each year of requested support may not exceed the \$150,000 or \$300,000 direct cost limit, whichever is applicable.

C. Eligibility

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

D. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, a second or third year of noncompetitive continuation of support will depend on: (1) Performance during the preceding year, (2) compliance with regulatory requirements of the investigational new drug (IND)/investigational device

exemption (IDE), and (3) availability of Federal funds.

E. Funding Plan

The number of studies funded will depend on the quality of the applications received and the availability of Federal funds to support the projects. Resources for this program are limited. Therefore, if two applications propose duplicative or similar studies, FDA may support only the study with the better score. Funds may be requested in the budget to travel to FDA for meetings with OPD or reviewing division staff about the progress of product development.

Before an award will be made, the OPD will confirm the active status of the protocol under the IND/IDE. If the protocol is under FDA clinical hold for any reason or if the IND/IDE for the proposed study is not active and in regulatory compliance, no award will be made. Documentation of assurances with the Office of Human Research Protection (OHRP) (see section III.A of this document) should be on file with the FDA grants management office before an award is made. In order to avoid funding studies that may not receive or may experience a delay in receiving institutional review board (IRB) approval, documentation of IRB approval for all performance sites must be on file with the FDA grants management office before an award to fund the study will be made. In addition, if a grant is awarded, grantees will be informed of any additional documentation that should be submitted to FDA's IRB. This grant program does not require the applicant to match or share in the project costs if an award is made.

F. Dun and Bradstreet Number (DUNS)

Beginning October 1, 2003, applicants will be required to have a DUNS number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

III. Human Subject Protection and Informed Consent

A. Protection of Human Research Subjects

All institutions engaged in human subject research supported by the Department of Health and Human

Services (DHHS) must file an "assurance" of protection for human subjects with the OHRP (45 CFR part 46). Applicants are advised to visit the OHRP Internet site at <http://ohrp.osophs.dhhs.gov/> (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**) for guidance on human subjects issues. The requirement to file an assurance applies to both "awardee" and collaborating "performance site" institutions. Awardee institutions are automatically considered to be engaged in human subject research whenever they receive a direct DHHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears the responsibility for protecting human subjects under the award. The awardee institution is also responsible for, among other things, ensuring that all collaborating performance site institutions engaged in the research hold an approved assurance prior to their initiation of the research. No awardee or performance site institution may spend funds on human subject research or enroll subjects without the approved and applicable assurance(s) on file with OHRP.

Applicants should review the section on human subjects in the application instructions entitled "I. Preparing Your Application, Section C. Specific Instructions, Item 4, Human Subjects" for further information.

The clinical protocol should comply with ICHG6 "Good Clinical Practice Consolidated Guidance" which states an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Applicants are encouraged to review the regulations, guidances and information sheets on Good Clinical Practice cited on the Internet at <http://www.fda.gov/oc/gcp/>.

B. Key Personnel Human Subject Protection Education

The awardee institution is responsible for ensuring that all key personnel receive appropriate training in their human subject protection responsibilities. Key personnel include all principal investigators, coinvestigators, and performance site investigators responsible for the design and conduct of the study. Neither DHHS, FDA, nor OPD prescribes or endorses any specific education programs. Many institutions have already developed educational programs