

staff about the appropriateness of the proposal to the goals of the OPD grant program described in section I of this document.

V. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 5/01) or the original and two copies of PHS 5161-1 (Rev. 7/00) for State and local governments, with three copies of the appendices must be submitted to Maura Stephanos (see **ADDRESSES**). State and local governments may use the PHS 398 (Rev. 5/01) application form in lieu of the PHS 5161-1. Other than evidence of final IRB approval, no material will be accepted after the receipt date. The mailing package and item two of the application face page must be labeled "Response to RFA-FDA-OPD-2004-1" or "RFA-FDA-OPD-2005-1," whichever is applicable. If an application for the same study was submitted in response to a previous RFA but has not yet been funded, an application in response to this notice will be considered a request to withdraw the previous application.

Also, if an application is submitted for the October 13, 2003, due date and is not funded, and an application for the same study is then resubmitted for either the April 7, 2004, or October 6, 2004, due dates for FY 2005 funding, the original, unfunded application will be administratively withdrawn. Resubmissions are treated as new applications; therefore, the applicant for a resubmitted application must address the issues presented in the summary statement from the previous review, and include a copy of the summary statement itself as part of the resubmitted application. Applicants must follow guidelines named in the PHS 398 (Rev. 5/01) grant application instructions.

VI. Method of Application

A. Submission Instructions

Applications will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday until the established receipt dates. Applications will be considered received on time if hand delivered to the address noted previously before the established receipt dates or sent or mailed by the receipt date as shown by a legible U.S. Postal Service dated postmark or a legible dated receipt from a commercial carrier. 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 the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office). Please do not send applications to the CSR at NIH. Any application sent to NIH that is forwarded to FDA and received after the applicable due date will be judged nonresponsive and returned to the applicant. Applications must be submitted via U.S. mail or commercial carrier or hand delivered as stated previously. Currently, FDA is unable to receive applications electronically.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/01). Applications from State and local governments may be sent on Form PHS 5161-1 (Rev. 7/00) or Form PHS 398 (Rev. 5/01). All "General Instructions" and "Specific Instructions" in the application kit or on the OPD Web site (see **ADDRESSES**) must be followed except for the receipt dates and the mailing label address. The face page of the application must reflect the request for applications number RFA-FDA-OPD-2004-1 or RFA-FDA-OPD-2005-1, whichever is applicable. The title of the proposed study must include the name of the product and the disease/disorder to be studied and the IND/IDE number. The remaining portion of the application may not exceed 100 pp. in length and must be single-spaced, printed on 1 side, in 12-point font, and unbound.

Applicants have the option of omitting from the application copies (but not from the original) specific salary rates or amounts for individuals specified in the application budget and Social Security numbers if otherwise required for individuals. The copies may include summary salary information.

Applicants should provide as an appendix to the application a summary of any meetings or discussions about the clinical study that have occurred with FDA reviewing division staff.

Data and information included in the application will generally not be publicly available prior to the funding of the application. After funding has been granted, data and information included in the application will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (including inter alia 21 CFR 20.61).

Information collection requirements requested on Form PHS 398 (Rev. 5/01) have been sent by the PHS to the Office of Management and Budget (OMB) and

have been approved and assigned OMB control number 0925-0001. The requirements requested on Form PHS 5161-1 (Rev. 7/00) were approved and assigned OMB control number 0348-0043.

VII. Reporting Requirements and Monitoring Activities

The original and two copies of the annual Financial Status Report (FSR) (SF-269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. For continuing grants, an annual program progress report is also required. For such grants, the noncompeting continuation application (PHS 2590) will be considered the annual program progress report. Also, all new and continuing grants must comply with all regulatory requirements necessary to keep active status of their IND/IDE. Failure to meet regulatory requirements will be grounds for suspension or termination of the grant.

The program project officer will monitor grantees quarterly and will prepare written reports. The monitoring may be in the form of telephone conversations or e-mails between the project officer/grants management officer and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the grant, including those which state that future funding of the study will depend on recommendations from the OPD project officer. The scope of the recommendations will confirm that: (1) There has been acceptable progress toward enrollment, based on specific circumstances of the study; (2) there is an adequate supply of the product/device; and (3) there is continued compliance with all FDA regulatory requirements for the trial.

The grantee must file a final program progress report, FSR and invention statement within 90 days after the end date of the project period as noted on the notice of grant award.

VIII. Clinical Trials Data Bank

The Food and Drug Modernization Act of 1997 requires studies of drugs for serious or life-threatening diseases conducted under FDA's IND regulations to be entered into the Clinical Trials Data Bank (CTDB).