SMG 2150.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

GRANTS ADMINISTRATION

GRANTS AND COOPERATIVE AGREEMENTS

Transmittal Number 91-63 -- Date: 06/26/1991

1. PURPOSE

The purpose of this guide is to (1) describe the grant and cooperative agreement: review and award process and (2) establish the areas of responsibility for the award and administration of grants and cooperative agreements.

2. BACKGROUND

Extramural activities (that is, where funding is provided to an organization outside the agency) are a principal vehicle for accomplishing the mission and

goals of the Food and Drug Administration (FDA) and its component Centers. FDA may fund extramural activities by using instruments reflecting either a procurement or an assistance relationship. These instruments are different in purpose and application and create different relationships between the parties.

A. **Procurement (Contracts).** A contract is used when the principal purpose of the transaction is to acquire a specific service or end product for the direct benefit of, or use by the FDA.

B. **Assistance (Grants and Cooperative Agreements)**. An assistance mechanism is used when the principal purpose of the transaction is to transfer money or property to a recipient to accomplish a public purpose authorized by statute or law.

   This guide deals only with FDA's assistance mechanisms (that is grants and cooperative agreements). There are a number of terms most commonly used in the award and administration of FDA grants and cooperative agreements (Attachment A).

3. POLICY

It is the policy of FDA to use the assistance mechanism to support research, conferences, and other activities when the primary objective is to accomplish a public purpose authorized by statute or law. The two types of assistance funding mechanisms used by the FDA include the grant and cooperative agreement. Grants are used when (1) the FDA awarding office anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities, thus allowing the recipient freedom of action in carrying out the project; and (2) there is no expectation on the part of the funding agency of a specific service or product. Cooperative agreements are used when substantial program involvement is anticipated between the FDA and the recipient during the performance of the activity.

4. AUTHORITY

The authority under which research grants and cooperative agreements are issued by the FDA is the Public Health Service Act, Public Law 78-410, Title III, Section 301(c) as amended, 356, 1702 and 1704 and the Radiation Control for Health Safety Act of 1968, Public Law 90-602 and Section 5 of the Orphan Drug Act (21 U.S.C. 360ee).

5. SUBMISSION OF APPLICATIONS

A. **Solicited Applications.** Competing applications for FDA programs are solicited through request for applications (RFA) published in the Federal

Register and must be submitted to the Division of Contracts and Grants Management on Application for Public Health Service Grant, Form PHS 398. Non-competing continuation applications are submitted on Application for Public Health Service Grant, Form PHS 2590.

B. Unsolicited Applications. Unsolicited grant applications are submitted to the Division of Research Grants (DRG) at the National Institutes of Health (NIH). The DRG/NIH serves as the administrative coordinating center for all FDA unsolicited grant applications. The DRG Assignment Officer, based on his/her review, assigns each competing application to (1) a specific primary and often secondary funding NIH Bureau, Institute or Division (BID) or other PHS Sponsoring Agency and (2) an Initial Review Group (IRG) for scientific review. The review by the DRG Assignment Officer is based on program relevance as defined in the NIH/DRG Referral Guidelines. The application is then given an identification number, checked for completeness, relevant data entered into the Grants Information System (IMPAC), and copies are forwarded to the appropriate IRG, NIH or other PHS Agencies for internal logging, distribution, and review (Attachment B).

C. Nonresponsive Applications. Nonresponsive applications are those which are determined to be ineligible for consideration by the IRG. DCGM shall review all applications to determine if they meet the eligibility criteria as published in the Federal Register (FR). Once an application is determined to be eligible for competition, it is reviewed by program staff to determine if it is scientifically responsive to the RFA. Applications which are determined to be nonresponsive shall be returned to the applicant within thirty days (30) of receipt accompanied by a letter of explanation signed by the Agency Grants Management Officer (GMO).

D. Application Receipt Point. The State Contracts and Assistance Agreements Branch (SCAAB), Division of Contracts and Grants Management (DCGM), FDA, is the official receipt point for the receipt of all applications in response to a Request for Application (RFA) and those applications referred to the FDA by DRG/NIH.

6. COMPETITIVE REVIEW OF APPLICATIONS

FDA Grants and Cooperative Agreements Policy includes a dual review. The dual review procedure consists of an initial review group, referred to as a "Study Section", or independent field readers and a second level group referred to as the Council or in the case of CDRH, members of the Center's own staff.

A. Initial Review.

1. Solicited Applications. The initial review of solicited applications is performed by an ad hoc review committee or the necessary review may be obtained by using an established list of field reviewers to whom applications are sent for evaluation and comment in lieu of review by committee. The Center must obtain advanced approval from the GMO before using field readers. In accordance with PHS Policy, the authority to appoint reviewers may not be assigned below the level of Center/Program or Institute Director (or acting designee) for headquarters agencies. However, nominations for reviewers may originate at any level.

2. Unsolicited Applications. The initial review of unsolicited applications may be performed by a DRG/NIH Initial Review Group (IRG) also known as a "Study Section". In special circumstances, DRG may be requested to assign FDA as primary and therefore responsible for the initial review.

The initial review has as its primary function the review and evaluation of the scientific merit of research grant applications. A minimum of three (3) completed reviews are required for each application. Reviewers may recommend a grant application for:

1. **Approval.** The application has been judged to meet relevant review criteria. A vote for approval is equivalent to a recommendation that an award be made provided sufficient funds are available. A priority rating must be given.

2. **Disapproval**. The application has been judged deficient in its scientific, technical, or managerial aspects and thus not worthy of support. No priority rating is required.

3. **Deferral.** The final recommendation has been postponed in order to obtain additional information or otherwise augment the review of the application. Deferred applications are not presented to Council and are usually reviewed again at the next IRG meeting.

   Usually, recommendations on solicited applications are limited to approval or disapproval.

   For each application recommended for approval, each ad hoc reviewer individually and privately records a numerical rating that reflects his or her own opinion of the scientific merit relative to the "state of the art" of the proposed research. The numerical rating ranges from 100 (the best) to 500 (the least meritorious). If a majority of the reviewers vote

for disapproval, program staff will not record a score and the record will show disapproval. If a minority of the reviewers vote for disapproval, program staff shall record a score of 500, to be used for calculation purposes only.

Summary Statements. After the initial review, the program resource person who is serving as Executive Secretary to the panel prepares Summary Statements (often referred to as "pink sheets") for each application. The summary consists of a concise statement of the proposed research, critique and evaluation of its component parts, and the recommendation of the reviewers. Summary Statements on applications recommended for approval contain a priority score and a recommended budget for the initial year and future years of support. A separate minority critique must also be provided if two or more reviewers voted against the majority recommendation. A roster of reviewers will be maintained in the program file. DCGM staff will dispose of Individual reviewers' written comments and other notes after the Summary Statement has been prepared in final form.

B. Second Level Review.

The second step in the dual review process is the Council review. The FDA currently uses the National Advisory Environmental Health Sciences Council (NAEHSC) to provide the second level review for FDA's grant and cooperative agreement applications for all Centers except the Center for Devices and Radiological Health (CDRH) and those applications which are to be funded under the authority of the Radiological Health Safety Act. CDRH uses members of its own staff to perform the second level review function for radiological health applications.

Second level review recommendations are based not only on considerations of scientific merit, as judged by the initial reviewers, but also on the relevance of the proposed study to the Agency's program and priorities. Council is not charged with the scientific assessment of the details of each individual application, but does have, as part of its mission to assure itself of the adequacy of the initial review. There are certain situations in which Council may wish to review and discuss an individual application, some examples are:

- applications requesting unusually large fiscal commitments; applications from foreign institutions;

- instances of split vote, ethical issues, human subjects, animal welfare, or similar issues;

- any application previously deferred for additional information or re-review;

- any application identified by staff as requiring special consideration or discussion by Council. These are generally identified by a - memo from staff to Council summarizing the concerns of staff; and

- any applications that have been identified by members of Council as special concern or as posing special policy issues.

Occasionally, situations may arise in which Council members question the recommendation of the initial reviewers or question the competence of the initial reviewers in the specific expertise necessary for review of the application. When Council does not accept the recommendation of the initial reviewers' approval or disapproval of the scientific/technical merit of an application, the Council will defer action on the application and return it for re-review by the same reviewers or a different group of reviewers. Following a second review by Council, its recommendation will be final.

In the case of an application with a recommendation from the initial review group involving a split vote, the Council may accept the minority opinion without returning the application for additional consideration.

7. FUNDING DECISIONS

A. Application Ranking. Immediately following the second level review applications are reviewed by appropriate Center staff and approved applications ranked for award. Separate ranking lists are prepared for solicited and unsolicited applications. The approved applications are ranked in priority order from most meritorious to least. The ranking list must also interdigitate those applications previously approved but not funded which were administratively carried forward for funding consideration. The ranking list must be signed by the Center Director (CD) (or acting designee) and the GMO. The original copy of the ranking list is maintained by the SCAAB. Approved unfunded applications may remain in competition for one year from the date of notification. Applications not funded within that time frame or withdrawn, based upon written notification by the applicant, will be administratively withdrawn from further consideration and destroyed.

B. Application Selection. Generally, Center staff select applications for award in straight priority order. However, they may choose to skip over one or more applications in order to fund a lower priority application which may be more critical to the objectives of the program. If this situation occurs, a justification for funding the application out of rank order must be signed by the CD (or acting designee) and provided to the GMO. The

justification should include a statement of the reasons which influenced the decision and a comparison with any higher ranked application(s) that are not being approved for funding.

C. Pay Memorandum. After funding decisions have been made, the responsible official within the Sponsoring Office will prepare a pay memorandum (Attachment C) to the Chief, SCAAB, DCGM, requesting the award of a particular grant. The pay memorandum must contain the following information:

- application number;
- name of the applicant organization;
- proposed start date and length of budget and project periods;
- amount of proposed grant award (direct costs only);
- any special conditions associated with the approval of the application and/or if direct costs are less than recommended, an
- explanation for the specific deletions;
- name and telephone number of the individual assigned as having programmatic responsibility for the grant; and
- appropriate accounting data.

The pay memorandum must be signed by the responsible individual within the Center and received in SCAAB at least fifteen (15) days prior to award. A copy of the ranking list and, if applicable, any necessary justification for funding out of priority order must be attached to the pay memo. Only upon receipt of a formally executed pay memorandum will the Chief, SCAAB, initiate processing of the Approval List and Notice of Grant Award (NGA) (Section 9).

8. NOTIFICATION TO APPLICANTS

Within 30 days after the Council meeting a written notice is sent to each unsuccessful applicant. Such notices shall also be sent to applicants whose applications have been deferred. The letters shall be prepared by the Centers with as much specificity as possible regarding the reasons for the adverse action. The GMO shall review and initial all deferral/disapproval letters before they are forwarded to the applicant (Attachment D).

9. AWARD AND OBLIGATION OF FUNDS

Upon receipt of the pay memorandum, the SCAAB, DCGM, will, in conjunction with the Project officer or other designated program person, negotiate the approved level of funding with the applicant; prepare the NGA and the Approval List (Attachments E, F and G).

A. Approval List. The Approval List is the official document which records the intent to fund and certifies the availability of funds (direct and indirect) to support the approved project. The document must be signed by the GMO, the CD or Deputy (or acting designee) and the Finance Officer. The Approval List must be fully signed before the NGA can be executed.

B. The Notice of Grant Award. The NGA is the official notification to the applicant that the project is being funded and, when signed by the GMO, serves as the official obligating document. The document shows the authorized direct costs by budget category, thereby constituting prior approval for performance of activities and the expenditure of funds for specific purposes and items described in the application agreed upon during the budget negotiations. Indirect costs are also reflected as well as the period of support, amounts recommended for future support and any special terms and conditions or restrictions under which the grant is awarded. The NGA is executed by the GMO after assurance of the following:

- the choice of the assistance mechanism was proper;
- the application was "peer" reviewed;
- the applicant institution is judged to have (or expected to acquire) adequate business management capability to administer the grant;
- the award is being made under the terms and conditions specified for the particular program and is consistent with appropriate review recommendations;
- the award is consistent with governing legislation, regulations and policies; and
- all review and award actions are adequately documented in the official grant files.

For awards resulting from applications referred to FDA by the DRG/NIH, NGAs are prepared on Form PHS 1533. Awards resulting from solicited applications received directly from the applicant are prepared on Form PHS 5152-1 (Attachments E and F).

The completed NGA together with the Approval List is sent to the Accounting Branch where it is recorded as an obligation in the FDA official accounting records. Copies of the NGA are mailed to the grantee institution, the grantee business office and the principal investigator. Internal copies are distributed to appropriate FDA offices.

10. CONGRESSIONAL NOTIFICATION

The SCAAB, DCGM, provides the Congressional Liaison Office with notification, prior to release of the award information to the grantee, of all applicable grant awards resulting from competing applications and non-competing continuations which are funded in excess of $1 million. The notification is provided at least 48 hours before the issuance of the award so that the appropriate Members of Congress may notify their constituents.

11. PAYMENT

Assistance awards are normally entered into the Payment Management System (PMS). Grantees paid through PMS are eligible for advance payment either via letter of credit or direct draw down. Instructions are provided directly to the grantee by PMS.

When it is determined by DCGM that advance payment is not appropriate, individual awards may be put on a voucher system.

12. ACCEPTANCE OF AWARD

The grantee indicates acceptance of the general and special provisions of the award by drawing funds from the grant payment system or submission of a voucher for reimbursement of expenditures.

13. AREAS OF RESPONSIBILITY

A. Sponsoring Office(s). Each Center or Program Office in coordination with the GMO shall:

1. provide anticipated spending plan (updated each quarter) for the current fiscal year;

2. discuss and plan RFA for publication in the Federal Register (Attachment H);

3. prepare draft RFA for review and approval by GMO;

4. sign off on final draft prepared by Federal Register writers in ORA;

5. submit list of nominees to serve as field readers or ad hoc review panel members; provide letters of appointment and instructions to these members for the review; receive field readers or panel members reviews; prepare and submit to the GMO the official Summary Statements;

6. review those solicited and unsolicited applications referred to it by the SCAAB;

7. notify in writing all unsolicited applicants determined to be unfundable by the CD;

8. attend IRG meeting as program resource person(s);

9. attend Council meeting as program resource person(s) and be prepared to respond to inquiries by the Council on areas of programmatic or scientific relevance;

10. make funding decisions and develop special programmatic terms and conditions as necessary;

11. insure that all approved applications recommended for funding which involve human subjects are reviewed by the FDA Research Involving Human Subjects Committee; except for the Office of Orphan Product Development (OPD) grant applications which require approval from the applicant institution's IRB;

12. prepare pay memorandum;

13. obtain signature on the Approval List of responsible Center individual who is authorized to commit funds;

14. maintain ongoing programmatic monitoring during the award period;

15. coordinate all on-site monitoring plans with SCAAB;

16. identify potential programmatic problems or nonperformance by grantee; and

17. assist SCAAB in closing out expired grants and cooperative agreements by obtaining, reviewing and approving final program progress reports.

B. State Contracts and Assistance Agreements Branch (Grants Management Staff) shall:

1. coordinate and establish estimated funding levels for each program in accordance with the Center's spending plan;

2. have developed and published the RFA in the FR:

    a. coordinate development of RFA with Program Staff;

    b. review and approve draft RFA;

    c. forward draft RFA to FR writers in the Division of Regulations Policy, ORA to be formatted;

    d. review final document and develop transmittal note from OMO to the Commissioner for approval;

3. clear invitational letters and instructions to ad hoc reviewers or field readers, review and approve scoring sheets used by reviewers and insure there are no conflicts of interest by the reviewers;

4. monitor the objective review process;

5. review Summary Statements, prepare Council Books (when applicable) and transmit to Council for review and decision;

6. perform management review of applications to determine:

    a. eligibility of applicant to receive Federal grant funds;

    b. applicant organization's management structure and ability to administer Federal funds;

    c. cost analysis;

    d. compliance with Federal regulations and Department policies (Attachment I);

    e. grant award issuance; and

    f. the monitoring of the ongoing management and administration of funds by the grantee.

7. attend IRG and Council meetings as resource person(s);

8. clear letters signed by the CD to applicants which communicate results of review;

9. maintain official grant files;

10. serve as a mandatory control point for all official communications and contacts with the grantee which commit or may result in committing the agency to a change in the amount of the grant, the grant budget, or any terms and conditions of the grant. The GMO shall sign or countersign all such correspondence.

11. provide business management consultation and technical assistance on grant matters to internal staff, grantees and applicants;

12. coordinate with program staff, and perform on-site monitoring activities when necessary; and,

13. initiate closeout proceedings of official grant files.

ATTACHMENT A

DEFINITIONS

Preapplication - A statement in summary form of the intent of the applicant to request Federal funds. It is used to determine the applicant's eligibility; determine how well the proposed project can compete with other similar applications; and eliminate any proposals for which there is little or no chance for Federal funding before applicants incur significant expenditures for preparing an application. Preapplications are required for all construction projects for which the need for Federal funding exceeds $1,000,000. Preapplications may also be required for other grant programs at the option of the FDA awarding office.

Application - A formal request for FDA funds submitted on the appropriate application forms.

New - The original request for PHS Support for a particular project. (Form PHS 3981.

Competing Continuation - A request for additional years of support beyond which was previously recommended. (Form PHS 398).

Supplemental - A request for additional funds to meet the needs of a project, funds either for the current year of the grant or for any future years already recommended, or for both. (Form PHS 398).

Noncompetitive Continuation - A request for funds for future budget periods after the first budget period when a project is approved for a period of more than 1 year. (Form PHS 2590).

Approval List - The official document which records the intent to fund and certifies the availability of funds (direct and indirect) to support the approved project. The document is signed by the Grants Management Officer, the Center Director and the Financial Officer. [Form NIH-1957 (formerly PHS 1485)].

Cooperative Agreement - An award instrument reflecting an assistance relationship between the Agency and the recipient in which substantial programmatic involvement is anticipated between the Agency and the recipient during performance of the activity.

Executive Secretary - A federal official responsible for the peer review of grant applications. This individual coordinates the appointment of reviewers and writes the Summary Statement based upon comments from the reviewers. The Executive Secretary should be an individual knowledgeable in the program area to which the applications relate, and thus be qualified to prepare the Summary Statement. The individual shall not currently nor expect

in the foreseeable future, to become responsible for programmatic oversight of the projects to be funded.

Grant - An award instrument reflecting an assistance relationship between the Agency and the recipient, in which no substantial involvement is anticipated.

Grants Management Officer - The individual designated by the Agency to be responsible for assuring that both the Agency and the grantee meet all requirements of laws, regulations and formally established policies, in carrying out program activities.

Notice of Grant Award (NGA) - The legally binding document that serves as a notification to the recipient and others that a grant or cooperative agreement has been made, contains or references all terms of the award, and documents the obligation of Federal funds in the HHS accounting system.

Pay Memorandum (See Funding Decision) - Memorandum from the Sponsoring Office to the Chief, State Contracts and Assistance Agreements Branch, requesting the award of a particular grant and containing the necessary information to negotiate and issue the NGA.

Project Officer - The person designated by the Sponsoring Office to be responsible for monitoring the programmatic aspects of the grant or cooperative agreement.

Request for Applications (RFA) - A formal announcement published in the Federal Register which invites grant or cooperative agreement applications in a specific field of interest to the Agency. Summary

Statement (Pink Sheet) - A summarization of reviewers' comments by the Executive Secretary after each meeting/review. The summary consists of the proposed research, a critique and evaluation of its component parts and a recommendation for approval, disapproval or deferral. Summary Statements on proposals recommended for approval contain a priority score and a recommended budget for the initial year and future years of support. Summary Statements are provided to Council and subsequently to the Principal Investigator of the grant or cooperative agreement

ATTACHMENT B

REFERRAL MEMORANDUM

MEMORANDUM – Food and Drug Administration

DATE:

FROM: Chief, Grants and Assistance Agreements Section SCAAB, DCGM

SUBJECT: Application (s) 1 R01 FD 01464-01, 1 R01 FD 01466-01 Council Date: September 1989.

TO: Dr. Able Smith, CVM (HFV-500)

The subject unsolicited applications referred to FDA by the Division of Research Grants/NIH, for assignment (Special Review Committee by the Center for Veterinary Medicine) are being transmitted for review by your Center.

Please advise me, in writing, of the Center's interest and recommendations for these applications.

Joe Jones
Grants Management Officer

Attachments – 2 copies of each application

HFA-522: GAAS/SCAAB/DCGM:cld:9/6/90

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

ATTACHMENT D

NOTIFICATION LETTERS

John A. Smith, Ph.D.
Director, Research and Development
ABC Laboratories, Inc.
RD #6, Robinson Lane
Wappingers Falls, VA 12345

Reference: 1 R01 FD01234-01

Dear Dr. Smith:

The National Advisory Environmental Health Sciences Council reviewed your research grant application number 1 ROl FD01234-01 at its meeting on May 23, 1990. The Council did not recommend approval. You may be assured that this action will not affect the full consideration of other applications you may submit in the future.

The Advisory Council's action reflects the recommendation of the initial reviewers which evaluated the scientific merit of the proposal. The enclosed Summary Statement gives reasons for the unfavorable recommendation. If you wish to discuss the review of your application, please contact Dr. J. Jones at (301) 443-1234.

Sincerely yours,

Director,
Title of Participating Center

Enclosure

cc: John Doe
Chief Financial Officer

bcc: Official File, HFA-522
Dr. J. Jones

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

ATTACHMENT D

Dorothy A. Smith, Ph.D.
President
Consumer Health Information, Inc.
8350 Greensboro Drive, Suite 521
McLean, NC 22101

Reference: 1 R43 FD01234-01

Dear Dr. Smith:

The National Advisory Environmental Health Sciences Council recommended approval of your application number 1 R43 FDO1234-01 at its meeting on May 23, 1990. This letter, however, should not be construed to imply that an award will be made. It indicates only that your application was reviewed and recommended for approval. Therefore, since there is no assurance that a grant will be awarded, no publicity should be given to the approval nor any obligations incurred. Your application will remain in competition for funding for 12 months from the date of this letter. If, at the end of that time, funds have not become available for this project, your application will be administratively withdrawn.

We have enclosed a copy of the Summary Statement of the review of your application. Should you have any questions concerning your application or the review process, please feel free to contact Center Program Liaison, Dr. J. Jones, at (301) 443-1234.

Sincerely yours,

Director
Title of Participating Center

Enclosure

bcc: Official File, HFA-522
Dr. J. Jones

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

Attachment I

References

A. Section 301 of the Public Health Service Act (42 USC 241).

B. Section 356 of the Public Health Service Act (42 USC 263d).

C. Section 1702 of Title XVII of the Public Health Service Act (42 USC 300 U et seq).

D. Section 1704 of Title XVII of the Public Health Service Act (42 USC 300 U et seq).

E. Public Law 95-224, the Federal Grant and Cooperative Act of 1978.

F. HHS Grants Administration Manual Chapter 1-01, "Distinguishing Procurement and Assistance Relationships."

G. PHS Grants Administration Manual Chapter 1-507, "Objective Review of Grant Applications."

H. PHS Grants Administration Manual Chapter 1-64, "Ranking, Approval, and Funding of Grant Applications and Notification to Unsuccessful Applicants."

I. PHS Grants Administration Manual Chapter 1-03, "Grants Management Officer Responsibilities in the Administration of PHS Grants."

J. PHS Grants Administration Manual Chapter i:1-601, "Advance Notifications to the Congressional Liaison Office, OS, of PHS Grant Awards."

K. Staff Manual Guide FDA 2111.3, "FDA Research Involving Human Subjects Committee (RIHSC)."

L. Section 5 of the Orphan Drug Act (21 U.S.C. 360ee)