isolates per month to the regional laboratories, which measure susceptibility to a panel of antibiotics. Limited demographic and clinical information corresponding to the isolates are submitted directly by the clinics to CDC.

During 1986–1997, GISP has demonstrated the ability to effectively achieve its objectives. The recent emergence of resistance to fluoroquinolones, commonly used therapies for gonorrhea, has been identified through GISP and makes ongoing surveillance critical. Data gathered through GISP are used to alert the public health community to changes in antimicrobial resistance in *N. gonorrhoeae* which may impact treatment choices, and to guide recommendations made in CDC's STD Treatment Guidelines, which are published every several years. There is no cost to the respondents.

Respondent	No. of respondents	No. of responses/respondents	Avg. burden (in hrs.)	Total burden (in hrs.)
Laboratory	5	1056	1	5312
Clinic	26	204	0.166	8846
Total				6196

2. Tuberculosis Statistics and Program Evaluation Activity, Contact Follow-up (CDC 72.16) and Completion of Preventive Therapy (CDC 72.21)—(0920–0026)—Extension—The National Center for HIV, STD and TB Prevention (NCHSTP)—Tuberculosis (TB) is transmitted when contagious TB patients aerosolize *Mycobacterium tuberculosis* and susceptible persons (i.e., ''contacts'') are exposed. Some contacts are especially endangered by TB if they become infected—children younger than 5 years old, and anyone with an illness that weakens the immune system (e.g., the acquired immunodeficiency syndrome, AIDS). The prompt evaluation of all contacts is crucial for finding early TB cases and latent infections. For latent TB infections, treatment with isoniazid preventive therapy can prevent new TB cases from developing. Evaluation, follow-up, and preventive therapy for contacts comprise the most efficient approach for finding and treating recent TB infections and preventing future cases. Therefore, it is one of the highest priorities for the national TB control strategy, second only to finding and treating contagious cases. The local and the state TB control programs and CDC use Contact Follow-up (CDC 72.16) and Completion of Preventive Therapy (CDC 72.21) to measure progress in achieving the national goals for performance in these areas. There is no cost to the respondents.

Report	No. of respondents	No. of responses/respondent (in hrs.)	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Contact Follow-up (1996),	103	2	.5	103
Completion of Preventive Therapy (1995)	103	2	1	206
Total				309

Dated: June 26, 1998.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation,Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–17594 Filed 7–1–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Availability of Funds Program Announcement 98077, Programs To Prevent the Emergence and Spread of Antimicrobial Resistance in Food Animals

A. Purpose

The Centers for Disease Control and Prevention (CDC) is implementing a multifaceted effort to address the problem of antimicrobial resistance. As part of this, CDC, in collaboration with the Food and Drug Administration Center for Veterinary Medicine, announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program to provide assistance for the development and evaluation of demonstration projects to prevent and control the emergence and spread of antimicrobial resistance in food animals. CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information).

The purpose of this program is to develop, implement, and evaluate a prudent antimicrobial use project to reduce the emergence, prevalence, and spread of antimicrobial resistance among target pathogens in food animals.

The intention of this project is to develop and evaluate a ''prudent use of antimicrobial agents'' program in certain food animal groups. It is hoped that this project would serve as a model towards the long-term goal of development of a national campaign for prudent antimicrobial use in food animals, and that additional resources towards achieving this goal would be provided by veterinary and animal industry organizations.

Applicants should address the problem of antimicrobial resistance through interventions potentially including, but not limited to:

1. Promoting more judicious antimicrobial use (e.g., using antimicrobial agents only when needed, using appropriate doses of antimicrobial agents),

2. Reducing transmission of antimicrobial resistant microorganisms

among food animals through good management practices,

3. Preventing colonization and infection of animals by pathogens through the use of probiotics,

4. Improving the ability to provide effective narrow spectrum therapy by rapidly and accurately diagnosing resistant microorganisms through the use of improved laboratory testing procedures and improved quality and flow of laboratory data.

It is envisioned that funded projects will use a combination of approaches to achieve judicious antimicrobial use and other changes that will result in decreased appearance and spread of resistance. Funded projects will also be expected to conduct a multifaceted evaluation of many aspects of the program, including assessing the costs and any cost-savings associated with any proposed intervention.

B. Eligible Applicants

Applications may be submitted by public and private, nonprofit organizations and governments and their agencies in the United States. Thus, universities, colleges, research institutions, hospitals, other public and private non profit organizations, including State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply. Only one eligible application from an organization/government/agency will be accepted. Applicants from each organization/government/agency are encouraged to coordinate and combine their efforts prior to submitting their application.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant, contract, loan, or any other form.

C. Availability of Funds

Approximately $120,000 is available in FY 1998 to fund one or two awards. These resources will be provided to support demonstration projects in food animals (e.g. swine, poultry, beef cattle, dairy cattle). It is expected that the average annual award for projects will be range from $40,000 up to $70,000 and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change. It is expected that awards will begin on or about September 30, 1998. Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

Restrictions on Lobbying. Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Public Law 105–78) states in Section 503 (a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under A, below, and CDC shall be responsible for conducting activities under B, below.

A. Recipient Activities

Recipients are responsible for the following:

1. Develop study protocol to include utilizing the selected food animal (e.g., beef cattle, dairy cattle, swine, poultry); defining foodborne pathogens of interest (e.g., *Salmonella, Campylobacter*), and describing the partnerships (e.g., including a veterinary diagnostic laboratory, veterinary professional associations, and animal commodity groups).

2. Providing a descriptive analysis of the selected study population.

3. Defining, collecting, and analyzing baseline data, so that evaluation of the interventions can be done. This includes at a minimum collecting prevalence data on antimicrobial resistance among the target pathogens and measuring antimicrobial agent usage pattern before the intervention.

4. Designing and implementing an intervention promoting judicious antimicrobial use and other approaches to reducing antimicrobial resistance: It is anticipated that this will involve developing coalitions among veterinary professional societies, producers, commodity groups, and others, as well as implementing specific strategies. These strategies may include peer-education of veterinarians, producers, formulary guidelines, prescribing restrictions, and strategies which are likely to reduce transmission of pathogens. The choice of strategies should be justified based on the nature of the study population, and the infrastructure in which the study population receives veterinary care.

5. Measuring the effects of the intervention:

a. Measuring the change in rates of antimicrobial resistance of organisms over time. Organisms whose resistance can be measured could include: human foodborne pathogens, animal pathogens, organisms that are opportunistic human pathogens (e.g., *Enterococcus*), normal animal fecal flora.

b. Measurement of antimicrobial resistance should be accomplished by a laboratory with proven ability to perform measurements using a standard approved methodology, yielding a quantitative measure of resistance, such as mean inhibitory concentration or zone size.

c. As decreases in resistance as a result of the program may take several months to years to manifest themselves, recipients are responsible for measuring outcomes related to how well the interventions have been implemented.

d. Measuring cost implications of the intervention. This should include impact of the intervention on direct costs (*e.g.*, costs of antibiotics, veterinary care visits, duration of illness, etc.) and indirect costs (*e.g.*, lost productivity, decreased feed efficiency, etc.). Costs of the intervention program must be differentiated from those of the evaluation.

e. Consideration should be given to parallel measurements in a non-

intervention group of animals, to better define the impact of the intervention.

6. Dissemination of research findings: Disseminating research results by appropriate methods such as publication in journals, presentation at meetings, conferences, etc.

B. CDC Activities

CDC, in collaboration with Food and Drug Administration Center for Veterinary Medicine, will provide technical assistance in the design and conduct of the research. This includes: (1) providing technical assistance in the design and conduct of the project, including intervention methods and analytic approach; (2) performing selected laboratory tests as appropriate; (3) assisting in data management, the analysis of research data, and the interpretation and dissemination of research findings, as appropriate; (4) assisting in the design of the evaluation and in the identification of outcome measures that will allow for later analysis of economic benefits.

E. Application Content

All applicants must develop their application in accordance with the Form PHS–398 (revised 5/95), information contained in this cooperative agreement announcement, and the instructions outlined below. In order to ensure an objective, impartial, and prompt review, applications which do not conform to these instructions may be disqualified.

General Instructions

1. All pages must be clearly numbered.

2. A complete index to the application and its appendixes must be included.

3. The original and two copies of the application must be submitted unstapled and unbound. Bound materials (e.g., pamphlets, booklets, etc.) will not be accepted in the narrative or appendices. To submit such materials, copy them onto 8½″ × 11″ white paper, one-side only.

4. All materials must be typewritten, single spaced, and in unreduced type (no smaller than font size 12) on 8½″ by 11″ white paper, with at least 1″ margins, headers, and footers.

5. All pages must be printed on one side only.

Specific Instructions

The application narrative must not exceed 15 pages (excluding budget and appendixes). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below.

1. Abstract: Provide a brief (two pages maximum) abstract of the project.

2. Background and Need: Discuss the background and need for the proposed project. Illustrate and justify the need for the proposed project that is consistent with the purpose and objectives of this cooperative agreement program.

3. Capacity and Personnel: Describe applicant's past experience in conducting projects/studies similar to that being proposed. Describe applicant's resources, laboratory and other facilities, and professional personnel that will be involved in conducting the project. Include in an appendix curriculum vitae for all professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources that will be assigned to the project. Provide in an appendix letters of support from all key participating non-applicant organizations, individuals, etc., which clearly indicate their commitment to participate as described in the operational plan. Do not include letters of support from CDC personnel. Letters of support from CDC will not be accepted in the application.

4. Objectives and Technical Approach: Describe specific objectives for the proposed project which are measurable and time-phased and are consistent with the purpose and goals of this cooperative agreement program. Include a detailed timeline for completion of key activities. Provide a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all Recipient Activities. Include a clear description of applicant's technical approach/methods which are directly relevant to the study objectives. Clearly identify specific assigned responsibilities/tasks for all key professional personnel. Describe the nature and extent of collaboration with CDC and/or others during various phases of the project. Clearly describe the population to be studied (minimum adequate numbers of animals are as follows: dairy cows-100, turkeys or chickens-5000, beef cattle-500, and swine-250). Describe in detail a plan for evaluating study results (including how data on prescribing practices, costs, and charges will be obtained) and for evaluating progress toward achieving project objectives. Justify the choice of organisms and antimicrobial susceptibility that will be used for evaluation, and include a description about how quality of laboratory measurements will be assured.

5. Budget: Provide in an appendix a budget and accompanying detailed justification for the first year of the project that is consistent with the purpose and objectives of this program. Provide estimated total budgets for subsequent years. The last year may involve only data collection and analysis for purposes of evaluating the program. If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor, (2) breakdown and justification for estimated costs, (3) description and scope of activities to be performed by contractor, (4) period of performance, and (5) method of contractor selection (e.g., sole-source or competitive solicitation). (See sample budget included in application package.)

Note: If indirect costs are requested, a copy of the applicant organization's current negotiated Federal indirect cost rate agreement or cost allocation plan must be provided.

F. Application Submission and Deadline

The original and five copies of the completed application PHS Form 398 (revised 5/95, OMB Control Number 0925–0001) must be submitted to the address below on or before August 7, 1998:

Sharron P. Orum, Grants Management Officer, ATTN: Gladys T. Gissentanna, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305–2209

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications which do not meet the criteria in 1. a. or 1. b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

G. Evaluation Criteria

The applications will be reviewed and evaluated according to the following criteria by an independent review group appointed by CDC:

1. Background and Need (10 points):

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this program.

2. Capacity and Personnel (30 points total):

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. This includes the capacity to conduct quality laboratory measurements. (10 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research and programs related to that proposed as evidenced by curriculum vitae, publications, etc. (15 points)

c. Extent to which applicant includes letters of support from non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate the author's commitment to participate as described in the operational plan. (5 points)

3. Objectives and Technical Approach (60 points total):

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this program and which are measurable and time-phased. (10 points)

b. Extent to which the applicant identifies an appropriate population for study, including whether the results of a study in this population will be generalizable to other populations in the United States. Extent to which the applicant identifies microbes/resistance patterns for study that are of public health importance. (10 points) Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities. Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for developing and conducting the proposed program and evaluation and extent to which the plan is adequate to accomplish the study objectives. The extent to which applicant describes the existence of or plans to establish partnerships. (20 points)

c. Extent to which applicant describes adequate and appropriate collaboration with CDC and/or others during various phases of the project. (10 points)

d. Extent to which applicant provides a detailed and adequate plan for evaluating study results (including laboratory data, data on prescribing practices, and data on direct costs and charges and indirect costs), as well as plans for evaluating progress toward achieving project objectives. (10 points)

4. Budget (not scored):

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

H. Other Requirements

Technical Reporting Requirements

Semiannual progress reports are required and must be submitted no later than 30 days after each semiannual reporting period. The semiannual progress reports must summarize the following: (1) major accomplishments including information on women screened; (2) problems encountered in program implementation; and (3) efforts or proposed strategies to resolve problems. The final progress report is required no later than 90 days after the end of the project period. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement will be submitted with the progress reports.

An annual Financial Status Report (FSR) must be submitted no later than 90 days after the end of each budget period. The final financial status report is due no later than 90 days after the end of the project period.

An original and two copies of all reports should be submitted to the Grants Management Officer, Grants Management Branch, CDC.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order 12372 (E.O.). E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. Indian tribes are strongly encouraged to request tribal government review of the proposed application. If SPOCs or tribal governments have any process recommendations on applications submitted to CDC, they should forward them to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–18, Room 314, Atlanta, Georgia 30305. The due date for State process recommendations is 30 days after the application deadline date for new and competing continuation awards (the appropriation for this financial assistance program was received late in the fiscal year and would not allow for an application receipt date that would accommodate the 60-day State recommendation process period). The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date.

The following additional requirements, incorporated by reference, are applicable to this program. For a complete description of each, see Attachment 2 (included in the application kit).

AR98–2–Animal Subjects Requirements
AR98–9–Paperwork Reduction Act Requirements
AR98–10–Smoke-Free Workplace Requirements
AR98–15–Proof of Non-Profit Status (See Eligibility Section)

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act, as amended [42 U.S.C. 241(a) and 247b(k)(2)]. The Catalog of Federal Domestic Assistance Number is 93.283.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers

for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, Telephone (404) 842–6801, Email address: gcg4@cdc.gov.

Programmatic technical assistance may be obtained from Frederick Angulo, DVM, PhD, Medical Epidemiologist, National Centers for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop A–38, Atlanta, Georgia 30333, Telephone (404) 639–2840, Facsimile: (404) 639–2205, Email address: fja0@cdc.gov.

You may also obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

John L. Williams,

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

[FR Doc. 98–17592 Filed 7–1–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 98D–0375]

Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).'' Under the Sectoral Annex on Medical Devices (Medical Devices Annex), FDA has agreed to designate Conformity Assessment Bodies (CAB's). CAB's will be third parties (i.e., private individuals or organizations outside of FDA) authorized to perform premarket and quality system evaluations consistent with the Medical Devices Annex. Assuming the MRA enters into force and a final rule becomes effective, when finalized, this draft guidance will apply to CAB's seeking to be designated under the Medical Devices Annex, and it will assist those who are interested in participating in this program as CAB's or as applicants pursuing premarket and quality system evaluations consistent with the Medical Devices Annex.

DATES: Written comments by August 3, 1998.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the World Wide Web, submit written requests for single copies of the guidance document entitled ''Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)'' on 3.5'' diskette to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self addressed adhesive labels to assist that office in processing your request, or fax your request to 401–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in negotiations on an international agreement on medical devices concluded in June 1997 between the United States and the European Community (EC). These negotiations resulted in the drafting of the MRA, which includes a special section pertaining to medical devices and is referred to as the Medical Devices Annex. After completion of a 3-year transition period, the Medical Devices Annex provides for normal endorsement of premarket and quality system evaluation reports of conformity assessment produced by equivalent third parties, the CAB's.

The MRA was signed in London on May 18, 1998, but it has not entered into force. FDA has published a proposed rule on the portions of the MRA affecting FDA-regulated products (63 FR 17744, April 10, 1998); the comment period closed on May 11, 1998.

In order to establish confidence in the conformity assessment process, CAB's will be required to participate in rigorous joint activities to demonstrate their proficiency to conduct evaluations. Upon implementation of this program, CAB evaluations will be exchanged and normally endorsed by both FDA and the EC for the marketing of medical devices.

FDA intends to use the National Voluntary Conformity Assessment System Evaluation (NVCASE) administered by the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce to recognize one or more accreditation bodies that, in turn, will assess potential U.S. CAB's seeking to be designated under the Medical Devices Annex, to evaluate medical devices produced for the EC market. FDA will consider the recommendations made by the recognized accreditation bodies under NVCASE from June 1, 1998, to October 1, 1998, and then designate U.S. CAB's that meet criteria for technical competence established in the Medical Devices Annex. This draft guidance provides information regarding the process for CAB's to become eligible for designation under the Medical Devices Annex.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on guidance for staff, industry, third parties, and third party programs under the sectoral annex on medical devices to the Agreement on Mutual Recognition Between the United States of America and the European Community. 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 applicable statute, regulations, or both. This guidance is not final nor is it in effect at this time.

The agency has adopted Good Guidance Practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so using the World Wide Web. CDRH maintains