

The AHCPR research agenda is designed to be responsive to the needs of consumers, patients, clinicians and other providers, plans, purchasers, and policy makers for evidence-based information which they need in order to improve health care quality and outcomes, control costs, and assure access to needed services.

The PA sets out priority interests in research, demonstration, dissemination and evaluation projects under broad program areas as follows:

(1) Support improvements in health outcomes. AHCPR seeks to support research to better understand the outcomes of health care, at both the clinical and systems levels; and, in particular, what works, for whom, when, and at what cost.

(2) Strengthen quality measurement and improvement. This area of interest includes research on the use of evidence-based practice information.

(3) Identify strategies to improve access, foster appropriate use and reduce unnecessary expenditures. This area includes research on access, use, and cost of health services; organization, financing, and delivery; and primary care practice.

AHCPR has identified as a special focus of research across the major program areas, health issues related to priority populations, identified as minority populations, women, and children.

The PA also identifies as emerging research interests two additional areas that are becoming increasingly important in today's market-driven health care delivery system. These are research on methodologic advances in health services research, especially cost-effectiveness analysis, and research on ethical issues across the spectrum of health care delivery.

The AHCPR is encouraging research using data from the Medical Expenditure Panel Survey (MEPS), developed by AHCPR with collaboration by the National Center for Health Statistics, and other AHCPR-supported data bases such as the Health Care Cost and Utilization Project (HCUP-3).

Also encouraged are partnerships with private and public organizations to facilitate development and sharing of scientific knowledge and resources, including cost-sharing mechanisms; projects that will produce results within 2 to 3 years; and results that can be integrated rapidly into practice or policy.

Potential applicants and other interested organizations and individuals should obtain a copy of the complete PA for details on AHCPR interests, program

contracts, application procedures, and review and award criteria.

Dated: March 26, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98-8513 Filed 3-31-98; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No: CB-98-02]

Fiscal Year 1998 Discretionary Announcement and Request for Applications for Two National Technical Assistance Resource Centers, and Community-Based Family Resource Grants to Tribal and Migrant Populations

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Fiscal Year 1998 discretionary announcement and request for applications for two national technical assistance resource centers, and community-based family resource grants to tribal and migrant populations

SUMMARY: The Children's Bureau and its Office on Child Abuse and Neglect announce the availability of fiscal year 1998 funding and request for applications to support a National Resource Center for Programs Serving Abandoned Infants and Infants At Risk of Abandonment and Their Families (as authorized by Pub. L. 104-235, the Abandoned Infants Assistance Act of 1988, as amended); a National Resource Center for Community-Based Family Resource and Support Programs; and Grants to Tribes, Tribal Organizations, and Migrant Programs for Community-Based Family Resource and Support Programs (as authorized by the Child Abuse Prevention and Treatment Act, as amended by Pub. L. 104-235 [1996]).

Note: Pursuant to the Child Abuse Prevention and Treatment Act (CAPTA) Amendments of 1996 (Pub. L. 104-235), the Department of Health and Human Services announced in the December 8, 1997, **Federal Register**, the elimination of the National Center on Child Abuse and Neglect (NCCAN) and the consolidation of child abuse and neglect functions within the Children's Bureau.

STATUTORY AUTHORITY COVERED UNDER THIS ANNOUNCEMENT:

The Children's Bureau solicits applications under the authority of Pub. L. 104-235: the Abandoned Infants Assistance Act of 1988, as amended (42 U.S.C. 670) (CFDA: 93.551); and the Child Abuse

Prevention and Treatment Act (CAPTA), as amended in 1996 (42 U.S.C. 5101 *et seq.*) (CFDA: 93.590).

DATES: The closing date for the receipt of applications under this announcement June 1, 1998. In order to be eligible for competition, mailed applications must be POSTMARKED on or before this date, and hand delivered applications must be RECEIVED on or before this date.

ADDRESSES: Intent to Apply: If you are going to submit an application, call in the following information within two weeks of the receipt of this announcement: The name, address, and telephone number of the contact person; the name of the organization; and the priority area(s) in which you may submit an application or send a postcard with the information to: Administration on Children, Youth and Families (ACYF) Operations Center, 1225 Jefferson Davis Hwy, Suite 414, Arlington, VA 22202. The telephone number is 1-800-351-2293. This information will be used to determine the number of expert reviewers needed and to update the mailing list of persons to whom future program announcements will be sent.

Mailed Applications and Overnight/Express Mail Service: Mailed applications and applications delivered by overnight/express mail services shall be considered as meeting an announced deadline if they are *POSTMARKED* on or before the deadline date and sent to the Administration on Children, Youth and Families (ACYF) Operations Center, 1225 Jefferson Davis Hwy, Suite 414, Arlington, VA 22202. The telephone number is 1-800-351-2293. Any application *POSTMARKED* after the deadline date will not be considered for competition.

Hand Delivered Applications, Applicant Couriers: Applications *hand delivered by applicants or applicant couriers* shall be considered as meeting an announced deadline if they are *RECEIVED* on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., at the Administration on Children, Youth and Families (ACYF) Operations Center, 1225 Jefferson Davis Hwy, Suite 414, Arlington, VA 22202. The telephone number is 1-800-351-2293. Any application received after 4:30 p.m. on the deadline date will not be considered for competition.

Electronic Transmissions: ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted

regardless of date or time of submission and time of receipt.

Review Process: A panel of at least three reviewers (primarily experts from outside the Federal government) will review the applications. To facilitate this review, applicants should address each requirement under the Project Design, Results and Benefits, and Staff Background sections in detail. The reviewers will (1) determine the strengths and weaknesses of each application, using the evaluation criteria listed below; (2) provide verbal and written comments; and (3) assign numerical scores to each application. The point value following each criterion heading is the maximum score for that criterion.

Summary of Priority Areas and Funds Availability: The Children's Bureau and its Office on Child Abuse and Neglect are accepting applications in the following three Priority Areas:

Priority Area 1.01 National Resource Center for Programs Serving Abandoned Infants and Infants at Risk of Abandonment and Their Families

It is anticipated that one project will be funded as a cooperative agreement. Up to \$675,000 in Federal funds are available for the first 12 month budget year or \$2,700,000 for the four years of the project. Awards for subsequent budget periods, after the first year of the project, may exceed \$675,000 if such funds become available.

Eligible Applicants: Public or private nonprofit agencies, organizations, and institutions of higher education may apply.

Purpose: To provide training and technical assistance that will assist in the development, enhancement and coordination of services, exchange of information and the continuing development, expansion and strengthening and improvement in the quality and effectiveness of programs described in Pub. L. 104-235, the Abandoned Infants Assistance Act of 1988, as amended whether or not the service providers receive funds authorized under the Act. The Act provides financial support for demonstration projects to prevent the abandonment of infants and young children, particularly those with the human immunodeficiency virus (HIV) or who have been perinatally exposed to the virus or who have been perinatally exposed to a dangerous drug; to identify and address the needs of those infants and young children who are, or might be abandoned; to develop a program of comprehensive services for those children and their families which will strengthen family functioning and

prevent abandonment, including family foster care, case management, family support, parenting skills, in-home support services, respite and crisis intervention, counseling and group residential care services; to recruit and train health and social services personnel, foster care families and residential providers to meet the needs of infants and young children who are at risk of abandonment; and to develop permanency options for children who cannot return home.

Evaluation Criteria: (a) Objectives and Need for Assistance (20 Points)

The extent to which the applicant:

- Demonstrates the need for providing training and technical assistance to public and private agencies delivering services to drug and/or HIV-exposed children and families;
- Addresses the goals of the legislative mandate to meet the service needs of infants who have been exposed to a dangerous drug or who have been perinatally exposed to HIV/AIDS and who may be at risk of abandonment;
- Identifies the training and technical assistance goals that address the social service support needs of women impacted by substance-abuse and/or HIV/AIDS and for whom those supports will enhance family stability and functioning.
- Describes the objectives, goals and needs for training and technical assistance that address program/community/state needs on programming for the targeted families.

(b) Results and Benefits Expected (10 Points)

The extent to which the applicant:

- Identifies the results and benefits to be derived from the project and links these to the stated objectives;
- Describes how the lessons learned from the project will benefit policy, practice, theory and/or research in addressing the social service needs of substance-abusing or HIV/AIDS women and their families.

(c) Approach (40 Points)

The extent to which the applicant:

- Outlines a workable plan of action which relates to the stated objectives and scope of the project and reflects the intent of the legislative mandates;
- Details how the proposed work will be accomplished including a discussion of factors that might accelerate or decelerate the work;
- Lists the activities to be conducted in chronological order, showing a reasonable schedule of accomplishments and target dates;
- Describes any unusual features of the project, such as design or

technological innovations or reductions in cost or time;

- Describes a plan for providing technical assistance to AIA grantees on the required third-party evaluation efforts;
- Describes the kinds of third-party data to be collected from AIA-funded projects and describes a method of analysis for capturing the outcome indicators across the sites that reflect the achievements of the AIA-funded projects;
- Describes strategies that will assist the project in improving services to ensure permanency for infants and young children who are abandoned or are in danger of abandonment and in providing technical assistance regarding standby guardianships and testamentary planning; and
- Identifies each organization, agency, consultant or other key individuals or groups who will work on the project along with a description of the activities each will undertake and the nature of their effort or contribution.

(d) Staff and Position Data (10 Points)

The extent to which the applicant:

- Demonstrates that the proposed project director and key project staff, including evaluators, have the ability and experience to administer effectively and efficiently a project of this size, scope and complexity, including their experience and background in working with public and private programs providing social services and their familiarity with child welfare issues;

(e) Organization Profiles (10 Points)

The extent to which the applicant:

- Details the organization's experience in addressing the training and technical assistance needs of programs that serve women and families impacted by substance-abuse and/or HIV/AIDS; and
- Describes the adequacy of the applicant's management plan to ensure its capacity and efficiency to accomplish the goals of the project.

(f) Budget and Budget Justification (10 Points)

The extent to which the applicant justifies the following:

- Costs are reasonable in view of the activities to be conducted and the expected results and benefits;
- Salaries and fringe benefits reflect the level of compensation appropriate for the proposed staff responsibilities; and
- The non-Federal contribution of the total project costs.

Priority Area 1.02: National Resource Center for Community-Based Family Resource and Support Programs

It is anticipated that one project will be funded as a cooperative agreement. The maximum Federal share of this project is not to exceed \$300,000 for each 12-month budget period. The length of this project will be for 12 months, with non-competitive renewable funding at the same level for three additional 12-month periods, assuming satisfactory completion of the terms of the Cooperative Agreement on a year-by-year basis, and assuming the continued availability of funds for this program.

Eligible Applicants: Public or private nonprofit agencies, organizations, and institutions of higher education may apply. Collaborative efforts and interdisciplinary approaches are encouraged.

Purpose: The purpose of this Cooperative Agreement is to provide financial support for training and technical assistance to promote the purposes of the Community-Based Family Resource and Support (CBFRS) Grants program. This training and technical assistance is intended to build the capacity of CBFRS lead agencies to: (1) foster an understanding, appreciation, and knowledge of diverse populations in order to be effective in preventing and treating child abuse and neglect; (2) facilitate and assist efforts of State, local, Tribal, public, and private agencies in the interagency, interdisciplinary, coordinated planning and development of a Statewide Network of community-based, prevention-focused, family resource and support programs; (3) encourage public and private partnerships, including parents who are consumers, in the establishment and expansion of family resource and support programs; and (4) promote the development and implementation of lead agency program evaluation processes that include a peer review component.

Expected outcomes include the enhanced capacity of each State lead agency to engage in: (1) Developing and maintaining a Statewide Network of family support services; (2) conducting interagency needs assessments of required services; (3) facilitating CBFRS program and policy development; (4) coordinating the delivery of family resource services; and (5) conducting program evaluations that include a peer review component.

This project is expected to train and assist State lead agencies to establish effective interagency cooperation and collaboration that involves all

stakeholders, including families, and promotes public-private partnerships in the establishment and expansion of family resource and support programs. Training and technical assistance needs will be identified by State CBFRS lead agency staff in collaboration with ACYF Central and Regional Office personnel, and coordinated with other ongoing national training and technical assistance efforts. Training outcomes should be achieved through a combination of strategies, including on-site training, on and off-site technical assistance, and consultation with all appropriate stakeholder groups.

Evaluation Criteria: (a) Objectives and Need for Assistance (15 points). The application identifies the training and technical assistance objectives of the project which address: The plan for building the capacity of State, and local public and private agencies to create Statewide Networks of community-based, prevention-focused, family resource and support programs; and the training to enable CBFRS lead agencies to facilitate the development and implementation of evaluation processes that will determine the efficacy and impact of these networks and programs. Objectives must address each of the Project Design requirements of this priority area as described below. The applicant describes the need for providing training and technical assistance to public and private agencies linked to the CBFRS program, and demonstrates an understanding of the goals of the legislative mandate.

(b) Approach (35 points). The application outlines a workable plan of action which relates to the stated objectives and scope of the project and reflects the intent of the legislative mandates, which:

- Details how the proposed work will be accomplished including a discussion of factors that might accelerate or decelerate the work;
- Lists the activities to be conducted in chronological order, showing a reasonable schedule of accomplishments and target dates;
- Describes any unusual features of the project, such as design or technological innovations or reductions in cost or time;
- Describes a plan for providing technical assistance to CBFRS grantees on the development and implementation of evaluation processes that will determine the efficacy and impact of these networks and programs;
- Describes strategies for building the capacity of State, and local public and private agencies to create Statewide

Networks of community-based, prevention-focused, family resource and support programs; and for providing technical assistance to CBFRS lead agencies in this area;

- Provides a plan for promoting: (1) Interagency collaboration and implementation of new procedures for blending funding streams; (2) collaborative long-range planning of family support services and service delivery options; and (3) management improvement strategies that facilitate interagency coordination;
- Describes a plan to establish an advisory board that will provide overall program direction and guidance to the activities of the Center, and strategies for efficiently and effectively utilizing their expertise;
- Provides a plan to help lead agencies develop a child-focused, family-centered approach to the delivery of family support services, that reinforces and complements the State's efforts to provide services to preserve and support families, and emphasizes the prevention of child abuse and neglect;
- Provides a plan for coordinating activities with other National Resource Centers and Clearinghouses funded by the Children's Bureau and other sources;
- Describes a plan for ensuring that the Resource Center's services, program activities, and materials developed are provided in a manner that is racially and culturally sensitive to the population being served;

(c) Results or Benefits Expected (20 points). The application identifies the results, benefits, and level of customer satisfaction to be derived by lead agencies for the CBFRS program and their State and local constituents, and proposes measurement procedures for each; the extent to which the results and benefits are consistent with the stated objectives; the extent to which results and benefits contribute to lead agency policy and practice; and the extent to which the training and technical assistance project costs are reasonable in view of the expected results.

(d) Evaluation (10 points). The applicant provides an evaluation plan which:

- Includes methods and criteria to evaluate the results and benefits of the technical assistance project in terms of its stated objectives;
- Addresses both process and outcome evaluation;
- States goals and objectives in specific measurable form to document change, improvement, or effectiveness;

—Identifies the kinds of data to be collected.

(e) Staff and Position Data (10 points). The application identifies the educational and professional background of the project director and key project staff to demonstrate the applicant's ability to administer and implement the project effectively and efficiently. The role of the author(s) of the proposal, including ongoing involvement in the implementation and/or administrative structure is explicitly identified.

(f) Organization Profiles (10 points). The application identifies the experience of the organization which most clearly demonstrates the applicant's ability to administer and implement the project effectively and efficiently; and provides documentation of the applicant agency's experience in: (1) Identifying the training and technical assistance needs of an agency or organization; (2) developing or participating in the development of a plan to meet those needs; (3) recruiting, assigning, and deploying staff with appropriate experience in the delivery of training and technical assistance; and (4) designing, developing, delivering and evaluating training materials.

Priority Area 1.03: Grants to Tribes, Tribal Organizations, and Migrant Programs for Community-Based Family Resource and Support Programs

It is anticipated that three grants (one each to a tribe, a tribal organization, and a migrant program) will be funded under this announcement. The Federal share of this project will be \$109,450 per grantee for fiscal year 1998. The maximum Federal share of this project is not to exceed one-third ($\frac{1}{3}$) of one percent (1%) of the Federal appropriation for Title II for each 12-month budget period. It is anticipated that three grants of \$109,450 (one each to a tribe, a tribal organization, and a migrant program) will be funded under this announcement. Applicants must specify if they are applying as a "Tribe" or "Tribal Organization" or "Migrant Program".

Eligible Applicants: Indian tribes, tribal organizations, and migrant programs with the capacity to establish and maintain family resource services for the prevention of child abuse and neglect and linkages with the State Network of Community-Based Family Resource and Support Programs may apply. Collaborative efforts and interdisciplinary approaches are encouraged.

Purpose: The primary purpose of this priority area is to provide financial support to selected tribes, tribal

organizations, and migrant programs to develop linkages with the Community-based Family Resource and Support (CBFRS) State Network funded under Title II of CAPTA, and/or to provide services otherwise consistent with the purposes of the CBFRS. These funds must support more effective and comprehensive child abuse prevention activities and family support services that will enhance the lives and ensure the safety and well-being of migrant and Native American children and their families.

The purpose of the CBFRS program is to support State efforts to: (1) Develop, operate, expand, and enhance a network of community-based, prevention-focused, family resource and support programs that coordinate resources among a range of existing public and private organizations, and (2) foster an understanding, appreciation, and knowledge of diverse populations in order to be effective in preventing and treating child abuse and neglect.

Evaluation Criteria: (a) Objectives and Need for Assistance (15 points). The application identifies the training and technical assistance objectives of the project which address: The plan of the tribe, tribal organization or migrant program submitting the application to create linkages with the Statewide network of community-based, prevention-focused, family resource and support programs; and/or the provision of direct services that will increase the availability of child abuse prevention activities and family support services for the children and families served by the applicant agency. Objectives address each of the Project Design requirements of this priority area as described below. The applicant describes the need for providing family resource and support services, and demonstrates an understanding of the goals of the legislative mandate.

(b) Approach (35 points). The application outlines a workable plan of action which relates to the stated objectives and scope of the project, reflects the intent of the legislation, and which:

- Details how the proposed work will be accomplished including a discussion of factors that might accelerate or decelerate the work;
- Lists the activities to be conducted in chronological order, showing a reasonable schedule of accomplishments and target dates;
- Describes any unusual features of the project, such as design or technological innovations or reductions in cost or time;
- Provides a method to promote the applicant agency's communication

and coordination with other State and community agencies, that will ensure maximum utilization of a full continuum of community-based family resource and support programs, and ensure ease of access for the children, families, and professional staff served by the applicant agency.

—Provides a plan for assisting the State network of CBFRS lead agencies to improve their cultural competence, including promoting the ability of all participating agencies to serve all families effectively, make culturally appropriate placements, recruit and employ minority staff, deliver culturally relevant support services, and develop strategies to improve outcomes for minority families and children.

(c) Results or Benefits Expected (30 points). The application identifies the results, benefits, and level of customer satisfaction to be derived by the applicant agency's State and local constituents, and procedures to measure or evaluate each; the extent to which the results and benefits are consistent with the stated objectives; the potential impact of the results on agency policy and practice; and the extent to which the project costs are reasonable in view of the expected results.

(d) Evaluation (10 points). The application provides an evaluation plan which:

- Includes the methods and criteria to be used to evaluate the results and benefits of the project in terms of its stated objectives;
- Provides either a process or outcome evaluation;
- States goals and objectives in specific measurable form to document change, improvement, or effectiveness
- Identifies the kinds of data to be collected.

(e) Staff and Position Data (10 points). The application identifies the educational and professional background of the project director and key project staff to demonstrate the applicant's ability to administer and implement the project effectively and efficiently. The role of the author(s) of the proposal, including ongoing involvement in the implementation and/or administrative structure is explicitly identified.

(f) Organization Profiles (10 points). The application identifies the experience of the organization which most clearly demonstrates the applicant's ability to administer and implement the project effectively and efficiently; and provides documentation of the applicant agency's experience in:

(1) Provide direct services and coordinate with existing services that will prevent the occurrence or reoccurrence of child abuse and neglect; (2) provide direct or referral services that will support the safety and well-being of families; and (3) recruit, assign, and deploy staff with appropriate experience in the delivery of such services.

Application Guidelines, Forms and Assurances: To obtain a complete application package (including application guidelines, forms, and assurances) contact the National Clearinghouse on Child Abuse and Neglect Information at (800) 394-3366 or <nccanch@calib.com>. This application package consists of three parts. Part I provides information on the Children's Bureau and its Office on Child Abuse and Neglect and general information on the application procedures. Part II describes the review process, details regarding requirements for the grant applications, the criteria for the review and evaluation of applications, and the programmatic priorities for which applications are being solicited. Part III provides information and instructions for the development and submission of applications. The forms to be used for submitting an application are included in the application package. Applicants should note that grants to be awarded under this program announcement are subject to the availability of funds.

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center Technical Assistance Team at (800) 351-2293 is available to answer questions regarding application requirements and to refer you to the contact person in the Children's Bureau for programmatic questions.

Dated: March 23, 1998.

James Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 98-8559 Filed 3-31-98; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0184]

Rohm and Haas Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Rohm and Haas Co. has filed a

petition proposing that the food additive regulations be amended to provide for the safe use of completely hydrolyzed copolymer of acrylonitrile and trivinylcyclohexane ion exchange resin for use in treating potable water and aqueous, acidic, and alcoholic foods.

FOR FURTHER INFORMATION CONTACT:

Parvin M. Yasaei, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3189.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8A4588) has been filed by Rohm and Haas Co., 5000 Richmond St., Philadelphia, PA 19137. The petition proposes to amend the food additive regulations in § 173.25(a) (21 CFR 173.25(a)) to provide for the safe use of completely hydrolyzed copolymer of acrylonitrile and trivinylcyclohexane ion exchange resin for use in treating potable water and aqueous, acidic, and alcoholic foods.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 11, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-8512 Filed 3-31-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0188]

Guidance to Industry and CDRH for PMAs and PMA Supplements: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance to Industry and CDRH for PMAs and PMA Supplements: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review" (the CDRH draft guidance). The FDA Modernization Act

of 1997 (FDAMA) requires the agency to issue final guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application, specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application, and define supplemental applications that are eligible for priority review. This document is being issued as a draft guidance.

DATES: Written comments on the CDRH draft guidance must be received by May 1, 1998. Comments will be incorporated in a final guidance that is expected to be issued on May 20, 1998.

ADDRESSES: Submit written requests for single copies of the CDRH draft guidance entitled "Guidance to Industry and CDRH for PMAs and PMA Supplements: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review" 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 301-443-8818. Submit written comments on the CDRH draft 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. See the SUPPLEMENTARY INFORMATION section for electronic access to the CDRH draft guidance.

FOR FURTHER INFORMATION CONTACT:

Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(b) of FDAMA (Pub. L. 105-115) provides that no later than 180 days after the date of enactment, the Secretary shall issue final guidance to clarify the requirements for, and facilitate the submission of data to support the approval of supplemental applications for articles approved under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) or section 351 of the Public Health Service Act (42 U.S.C. 262). This provision of FDAMA requires the guidance to: