Services (DHHS) regulations. Are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (a) protections appear adequate, and there are no comments to make or concerns to raise, (b) protections appear adequate, but there are comments regarding the protocol, (c) protections appear inadequate and the Objective Review Group has concerns related to human subjects, or (d) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

9. Budget Justification (Not Scored) The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original and two copies of:

1. Semi-annual progress report (Attachment 2)

2. Financial Status Report (FSR) no more than 90 days after the end of the budget period

3. Final financial status report and performance report, no more than 90 days after the end of the project.

Send all reports to: Nelda Y. Godfrey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Cooperative Agreement Number: _____, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, Georgia 30341–4146.

The following additional requirements are applicable to this program. For complete description of each, see Attachment 1 in the application kit.

AR–1 Human Subjects Requirements

AR–2 Requirements of Inclusion of Women and Racial and Ethnic Minorities in Research

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2000

AR–17 Peer Review and Technical Reviews of Final

REPORTS OF HEALTH STUDIES—ATSDR

AR–18 ..	Cost Recovery—ATSDR.
AR–19 ..	Third Party Agreements—ATSDR.

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized in Sections 104(i)(1)(E) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) [42 U.S.C. 9604 (i)(l)(E) and (15)]. The Catalog of Federal Domestic Assistance number is 93.161.

J. Where To Obtain Additional Information

Please refer to Program Announcement 99059 when you request 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 the application kit please contact: Nelda Y. Godfrey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, Georgia 30341–4146, Telephone (770) 488–2722, E-mail address: nag9@cdc.gov.

To obtain technical assistance, contact: Sherri Berger, Epidemiologist, Health Investigations Branch, Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E–31, Atlanta, Georgia 30333, Telephone: (404) 639–5149, E-mail address: sob8@cdc.gov.

See also the CDC home page on the Internet: http://www.cdc.gov.

Dated: March 12, 1999.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 99–6712 Filed 3–18–99; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99002]

Public Health Conference Support Cooperative Agreement; Program for Human Immunodeficiency Virus (HIV) Prevention; Notice of Availability of Funds

A notice announcing the availability of Fiscal Year 1999 funds for the Human Immunodeficiency Virus (HIV) Prevention Public Health Conference Support Program was published in the **Federal Register** on March 10, 1998, [Vol. 64 FR No.46, pages 11911–11914] [FR Doc. 99–5867]. The notice is rescinded in its entirety, due to lack of funds.

Dated: March 15, 1999.

John L. Williams,

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

[FR Doc. 99–6734 Filed 3–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 99F–0461]

Ticona; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ticona has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 9B4644) has been filed by Ticona, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in Part 177 *Indirect Food*

Additives: Polymers (21 CFR 177) to provide for the safe use of polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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: February 26, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–6750 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0297]

Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' This draft guidance is intended to provide guidance for industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for resolving scientific and procedural disputes that cannot be resolved at the division level.

DATES: Written comments on the draft guidance document may be submitted by May 18, 1999. General comments on agency guidance documents are welcome at any time. Submit written comments on the information collection provisions by April 19, 1999.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, or FAX 888–CBERFAX or 301–827–3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Patricia L. DeSantis, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' The draft guidance is intended to provide guidance for industry on procedures that will be adopted by CDER and CBER for resolving scientific and procedural disputes that cannot be resolved at the division level. This draft guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist agency officials in resolving the issue(s) presented.

FDA regulations § 10.75 (21 CFR 10.75) provide a mechanism for any interested person to obtain formal review of any agency decision by raising the matter with the supervisor of the employee who made the decision. If the issue is not resolved at the primary supervisory level, the interested person may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's entire supervisory chain of command, through the centers to the Deputy Commissioner for Operations and then to the Commissioner. CDER and CBER regulations for dispute resolution during the investigational new drug (IND) process (§ 312.48 (21 CFR 312.48)) and the new drug application (NDA)/abbreviated new drug application (ANDA) process (§ 314.103 (21 CFR 314.103)) establish similar procedures for the resolution of scientific and procedural matters at the division level and subsequent formal review of decisions through center management.

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Pub. L. 105–115). Section 404 of the Modernization Act creates new section 562 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–1). Section 562 of the act provides that if, regarding an obligation concerning drugs or devices under the act or section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), there is a scientific dispute between the agency and a sponsor, applicant, or manufacturer, and no specific provision of the act or regulation provides a right of review of the matter in controversy, FDA shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of the controversy, including review by an advisory committee. Section 562 of the act further provides that such review of the controversy shall take place in a timely manner. In the **Federal Register** of November 18, 1998 (63 FR 63978), FDA amended § 10.75 to explicitly state that a sponsor, applicant, or manufacturer of a drug or device may request review of a scientific controversy by an appropriate advisory committee. In the preamble to the final rule, FDA stated that implementation of this provision would be undertaken by the individual FDA centers and would be described in guidance documents.

The Prescription Drug User Fee Act of 1992 (PDUFA) (Pub. L. 102–571) was reauthorized in November 1997 (PDUFA 2) as part of the Modernization Act. In conjunction with PDUFA 2, FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications as defined in section 735(1) of the act (21 U.S.C. 379g(1)) (PDUFA products). The PDUFA goals are summarized in ''PDUFA Reauthorization Performance Goals and Procedures,'' an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords. The PDUFA goals for major dispute resolution describe specific timeframes for CDER and CBER response to formally appealed decisions regarding scientific or procedural matters concerning PDUFA products.

The policies and procedures described in this draft guidance document will implement agency