

(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]

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## 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]

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## 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: