(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:

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.

The Center for Devices and Radiological Health (CDRH) draft guidance being issued at this time includes CDRH specific information as well as a copy of a draft guidance developed through a joint effort between the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The CDER/CBER draft guidance discusses the type of clinical evidence to support marketing applications for human drugs and biological products. Availability of the CDER/CBER draft guidance for comment was announced in the **Federal Register** of March 21, 1997 (62 FR 13650). The CDER/CBER draft guidance also explains those Centers' thinking on the use of literature to support effectiveness claims for drug and biological products.

Although the CDER/CBER draft guidance document does not address device issues directly, CDRH believes that the CDER/CBER draft guidance is broadly applicable to premarket approval applications (PMAs) and PMA supplements. In particular, the discussion of the use of published data to support approvals of supplements to approved products is consistent with the policies and regulations CDRH applies to its review of PMA supplements. The device industry should note that the examples provided in the attached CDER/CBER draft guidance were not developed with medical devices in mind and may not all be relevant to the evaluation of medical devices. CDRH has already issued guidance similar to the CDER/CBER draft guidance with respect to the design and analysis of clinical trials intended to support PMAs. That CDRH guidance also applies to the design and analysis of clinical trials submitted to support PMA supplements and is available on the internet at http://www.fda.gov/cdrh/manual/pmamanul.pdf.

CDRH recognizes that there are important differences between medical devices and drugs or biologics and differences in the legal standards for their approval. The CDRH draft guidance addresses those differences and includes explanation of the factors that go into the PMA review process. That discussion provides additional guidance on CDRH's policies and regulations intended to avoid duplication of previously submitted data. It also addresses the use of published literature to support PMAs and PMA supplements for marketing approval. The CDRH draft guidance refers readers to the Center's guidance on priority review and clarifies that it is applicable to determine which PMA supplements are eligible for priority review.

FDA anticipates that the final guidance to be issued by the agency on or before May 20, 1998, will apply to all products subject to premarket approval requirements, and will reflect and incorporate the comments received on the drug, biologic, and device sections.

II. Significance of Guidance

This guidance document represents the agency's current thinking on Guidance to Industry and CDRH for PMAs and PMA Supplements: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review. 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.

The agency has adopted Good Guidance Practices (GGPs), which 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 document is issued as a Level 1 guidance consistent with GGPs. Interested persons may, on or before May 1, 1998, submit written comments regarding this draft guidance.

III. Electronic Access

In order to receive the Guidance to Industry and CDRH for PMAs and PMA Supplements: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (620) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web for easy access to information text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance to Industry and CDRH for PMAs and PMA Supplements: Use of Published Literature, Recognition of Previously Submitted Materials, and Priority Review'', device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT-100 Compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1:FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS Topics Page, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH FOR GENERAL INFORMATION, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before May 1, 1998, submit to the Dockets Management Branch (address above) written comments regarding the CDRH draft guidance. Comments regarding the CDER/CBER draft guidance may be submitted, however, such comments must be limited to the guidance as it applies to PMAs and PMA supplementals. Such comments will be considered when determining whether to amend the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the CDRH draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–8568 Filed 3–27–98; 3:35 pm]

BILLING CODE 4160–01–F