application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than July 17, 1995.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. First Savings Financial Corp., Reidsville, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of First Savings Bank of Rockingham County, S.S.B. Reidsville, North Carolina.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. C. B. Bank Shares, Inc., Russiaville, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of Central Bank, Russiaville, Indiana.

C. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Watford City Bancshares, Inc., Watford City, North Dakota; to acquire 100 percent of the voting shares of First International Bank & Trust, Scottsdale, Arizona, a *de novo* bank.

Board of Governors of the Federal Reserve System, June 16, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–15295 Filed 6–21–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95F–0122]

Hempel Coatings (USA), Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hempel Coatings (USA), Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of meta-xylylenediamine and 3-diethylaminopropylamine as components of articles intended for food-contact use.

DATES: Written comments on the petitioner's environmental assessment by July 24, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

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 5B4457) has been filed by Hempel Coatings (USA), Inc., 6901 Cavalcade St., Houston, TX 77028. The petition proposes to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of meta-xylylenediamine and 3-diethylaminopropylamine as components of articles intended for food-contact use.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before July 24, 1995, submit to the Dockets Management Branch (address above) written comments. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 13, 1995.

Alan M. Rulis,

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

[FR Doc. 95–15348 Filed 6–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95F–0130]

Shell Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Shell Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyethylene terephthalate polymers in which the finished polymer contains less than 50 weight percent of ethylene-2,6-naphthalate as components of articles intended for food-contact use.

DATES: Written comments on the petitioner's environmental assessment by July 24, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

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 5B4450) has been filed by Shell Chemical Co., 130 Johns Ave., Akron, OH 44305–4097. The petition proposes to amend the food additive regulations in § 177.1630 *Polyethylene phthalate polymers* (21 CFR 177.1630) to provide for the safe use of polyethylene terephthalate polymers in which the finished polymer contains less than 50 weight percent of ethylene-2,6-naphthalate as components of articles intended for food-contact use.

The potential environmental impact of this action is being reviewed. To

encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before July 24, 1995, submit to the Dockets Management Branch (address above) written comments. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 13, 1995.

Alan M. Rulis,

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

[FR Doc. 95–15346 Filed 6–21–95; 8:45 am]

BILLING CODE 4160–01–F

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Orphan Products Development (OPD) grant program for fiscal year (FY) 1996. Previously, the $200,000 grant for phase 2 or 3 trials could only be awarded for a maximum of 2 years. Now all grants, including the $200,000 grant, may be awarded for a maximum of 3 years. This document is intended to inform eligible applicants of the application receipt dates, the estimated amount of funds available, the estimated number of awards to be made in FY 1996, and any changes in programmatic requirements, as well as to inform eligible applicants of the new extended length for all grants.

DATES: Application receipt dates are October 1, 1995, and January 15, 1996. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day.

ADDRESSES: Application forms are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Grants and Agreements Management Branch (HFA–520), Food and Drug Administration, Park Bldg., rm. 3–40, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

Note: Applications hand-carried or commercially delivered should be addressed to the Park Bldg., rm. 3–40, 12420 Parklawn Dr., Rockville, MD 20857. Do not send applications to the Division of Research Grants, National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Patricia R. Robuck, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 8–73, Rockville, MD 20857, 301–443–4903.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 15, 1994 (59 FR 41769), FDA announced that the agency would publish a notice annually in the **Federal Register** that references the August 15, 1994, standing announcement and reminds eligible applicants of: The receipt dates, the estimated amount of funds available, the estimated number of awards to be made during the fiscal year, and any changes in programmatic requirements or criteria. All provisions of the August 1994 standing announcement are applicable to the FY 1996 OPD grant program, except for the changes described below, and applicants should refer to the standing announcement for additional information. The OPD grant program standing announcement changes for FY 1996 are set forth below.

FDA is announcing the anticipated availability of funds for FY 1996 for awarding grants to support clinical trials on safety and effectiveness of products for rare diseases and conditions (i.e., those affecting fewer than 200,000 people in the United States). Contingent on availability of FY 1996 funds, it is anticipated that $12 million will be available for these grants, of which $6.2 million will be for noncompeting continuation awards. This will leave $5.8 million for funding the following: Approximately $2.9 million for 20 grants (phase 1, 2, or 3 trials) up to $100,000 each in direct costs per annum plus applicable indirect costs for up to 3 years, and approximately $2.9 million for 10 grants (phase 2 and 3 trials only) up to $200,000 each in direct costs per annum plus applicable indirect costs for up to 3 years. Applications exceeding this direct cost limit will be considered nonresponsive and will be returned to the applicant. The current, active investigational new drug (IND) or investigational device exemption (IDE) number for the proposed study must appear on the face page of the application with the title of the project.

In the **Federal Register** of August 15, 1994, under ''II. Human Subject Protection and Informed Consent,'' in section B. Informed Consent, the agency stated that consent and/or assent forms, and any additional information to be given to a subject should accompany the grant application. Under current procedures, consent and/or assent forms, and any additional information to be given to a subject, must be included in the grant application.

In addition, in the **Federal Register** of August 15, 1994, under ''V. Review Procedure and Criteria,'' in section B. Program Review Criteria, paragraph 3, the agency stated that if the sponsor of the IND/IDE is other than the principal investigator listed on the application, a letter from the sponsor verifying access to the IND/IDE is required. Under current procedures, if the sponsor of the IND/IDE is other than the principal investigator listed on the application, documentation must be provided in the grant application verifying that the grant applicant and the proposed protocol are included in the IND/IDE. Applications that do not have an active IND or IDE for the proposed study *at the time of application* will be considered nonresponsive.

In the same section, paragraph 4, the agency stated that the requested budget must be within the limits (either $100,000 in direct costs for up to 3 years or $200,000 in direct costs for up to 2 years) as stated in the request for applications. Under current procedures, the requested budget must be within the limits (either $100,000 in direct costs for any phase study or up to $200,000 in direct costs for studies in phase 2 or 3) as stated in the request for applications. The maximum study period will be 3 years.

The outside of the mailing package and item 2 of the application face page