

conditions and thereby have the potential to affect product safety, purity, or potency:

- (a) Use of a previously unapproved manufacturing area or facility;
- (b) Change in air quality, water quality, material, or personnel flow for licensed product manufacturing areas.
- (c) Change from single product manufacturing to multiple product manufacturing using same equipment and/or personnel.
- (d) Renovation to physical structure that alters product, material, and/or personnel flow.

xix. Addition to or replacement of an FDA-approved manufacturing step performed under contract to a second facility.

#### D. Categorization of Proposed Changes

Before implementing a change which is not identified above or does not clearly fit into one of the defined categories, manufacturers should discuss the proposed change with CBER. If guidance is not sought, the change should be reported in the form of a Category III supplement, subject to CBER approval prior to implementation.

Requests for information regarding categorization of proposed changes not included in the above categories may be addressed to the Director of the appropriate applications Division within the Office with assigned product, or establishment, responsibility at the Center for Biologics Evaluation and Research (HFM-99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

#### E. Information Requested for Category I Periodic Reports

FDA requests that manufacturers submit the following information for each Category I change in the order shown: (1) Name of the manufacturer; (2) the establishment license number; (3) the report dates (time period covered by the report); (4) the product(s) affected (list each one); (5) the change implemented, including: (a) A brief description and reason for the change and/or modification, (b) the establishment location involved, (c) the date the change was implemented, and (d) a cross-reference to the Approved Validation Protocol or Standard Operating Procedure, if applicable; and (6) the signature of the Responsible Head and the date signed.

Dated: March 31, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-8382 Filed 4-5-95; 8:45 am]

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#### [Docket No. 93F-0201]

#### Asahi Denka Kogyo K. K.; Withdrawal of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a

future filing, of a food additive petition (FAP 3B4378) proposing that the food additive regulations be amended to provide for the safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food to include the use at temperatures up to and including retort conditions.

#### FOR FURTHER INFORMATION CONTACT:

Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3092.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of July 29, 1993 (58 FR 40656), FDA announced that a food additive petition (FAP 3B4378) had been filed by Asahi Denka Kogyo K. K., c/o Japan Technical Information Center, Inc., 1002 Pennsylvania Ave. SE., Washington, DC 20003. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food to include the use at temperatures up to and including retort conditions. Asahi Denka Kogyo K. K. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7)

Dated: March 22, 1995.

**Eugene C. Coleman,**

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

[FR Doc. 95-8515 Filed 4-5-95; 8:45 am]

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#### [Docket No. 94F-0121]

#### BASF Corp.; Withdrawal of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B4384) proposing that the food additive regulations be amended to provide for the safe use of hydroxypropyl acrylate and butanediol diacrylate as monomers in the production of acrylic polymers intended for use in food packaging adhesives.

#### FOR FURTHER INFORMATION CONTACT:

Diane E. Robertson, Center for Food

Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of April 25, 1994 (59 FR 19730), FDA announced that a food additive petition (FAP 3B4384) had been filed by BASF Corp., 9401 Arrow Point Blvd., suite 200, Charlotte, NC 28273. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of hydroxypropyl acrylate and butanediol diacrylate as monomers in the production of acrylic polymers intended for use in food packaging adhesives. BASF Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 22, 1995.

**Eugene C. Coleman,**

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

[FR Doc. 95-8516 Filed 4-5-95; 8:45 am]

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#### Health Care Financing Administration

[BPO-130-N]

#### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Fourth Quarter 1994

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice lists HCFA manual instructions, substantive and interpretive regulations and other **Federal Register** notices, and statements of policy that were published during October, November, and December of 1994 that relate to the Medicare and Medicaid programs. Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe. We are also providing the content of revisions to the Medicare Coverage Issues Manual published between October 1 and December 31, 1994. On August 21, 1989, we published the content of the Manual (54 FR 34555) and indicated that we will publish