summary must include a description of the proposed services; a justification for the projected allocation for each component including relationship of funds allocated to numbers of clients served, characteristics of clients, duration of training and services, and cost per placement. In addition, the program component summary must describe any ancillary services or subcomponents such as day care, transportation, or language training.

X. Reporting Requirements

States are required to submit quarterly reports on the outcomes of the targeted assistance program, using Schedule A and Schedule C of the new ORR–6 Quarterly Performance Report form which was sent to States in ORR State Letter 95–35 on November 6, 1995.

Dated: March 26, 1997.

Lavinia Limon,

Director, Office of Refugee Resettlement.

[FR Doc. 97–8188 Filed 3–31–97; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 97F–0116]

Mitsui Petrochemical Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mitsui Petrochemical Industries, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 4-methylpentene-1 copolymers resulting from the copolymerization of 4-methylpentene-1 and 1-alkenes having from 12 to 18 carbon atoms for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by May 1, 1997.

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

FOR FURTHER INFORMATION CONTACT: Spring C. Randolph, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3191.

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 7B4534) has been filed by Mitsui Petrochemical Industries, Ltd., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to provide for the safe use of 4-methylpentene-1 copolymers manufactured by the catalytic copolymerization of 4-methylpentene-1 with 1-alkenes having from 12 to 18 carbon atoms in contact with food.

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 May 1, 1997, 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 the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 6, 1997.

Alan M. Rulis,

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

[FR Doc. 97–8115 Filed 3–31–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0125]

Roche Molecular Systems, Inc.; Premarket Approval of AMPLICOR® Mycobacterium Tuberculosis Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Roche Molecular Systems, Inc., Somerville, NJ for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the AMPLICOR® (MTB) Test. After reviewing the recommendation of the Microbiology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 26, 1996, of the approval of the application.

DATES: Petitions for administrative review by May 1, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon L. Hansen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION: On December 22, 1994, Roche Molecular Systems, Inc., Somerville, NJ 08876–3711, submitted to CDRH an application for premarket approval of the AMPLICOR® (MTB) Test. The device is a target amplified in vitro diagnostic test for the qualitative detection of *M. tuberculosis* complex DNA in concentrated sediments prepared from sputum (induced or expectorated), bronchial specimens including bronchoalveolar lavages or aspirates, or tracheal aspirates. The AMPLICOR® MTB Test is intended for use as an adjunctive test for evaluating acid fast bacilli (AFB) smear positive sediments prepared using NALC-NaOH or NaOH digestion-decontamination of respiratory specimens from untreated patients suspected of having tuberculosis. Untreated patients are patients who have: (1) Received no antituberculosis therapy; (2) had less than 7 days of therapy; or (3) have not received such therapy in the last 12 months. Only untreated patients may be evaluated with the AMPLICOR® MTB Test, which should only be performed in institutions proficient in the culture and identification of *M. tuberculosis* (ATS Level II and III or CAP extent 3 and 4). The test should always be performed in conjunction with a mycobacterial culture.

On January 25, 1996, the Microbiology Devices Panel of the Medical Devices Advisory Committee,

an FDA advisory committee, reviewed and recommended approval of the application. On November 26, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 1, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 20, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–8114 Filed 3–31–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0120]

Angelini Pharmaceuticals, Inc.; Premarket Approval of the 2-In-1 Drop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Angelini Pharmaceuticals, Inc., River Edge, NJ, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the 2-In-1 Drop. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 13, 1997, of the approval of the application.

DATES: Petitions for administrative review by May 1, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION: On May 25, 1994, Angelini Pharmaceuticals, Inc., River Edge, NJ 07661, submitted to CDRH an application for premarket approval of the 2-In-1 Drop. The device is a contact lens drop, packaged in a single-use container, that is indicated for use with soft (hydrophilic) contact lenses (including disposables) and rigid gas permeable contact lenses as a lubricating and rewetting agent during the wearing period and as a wetting agent to cushion lenses prior to placement on the eye. The 2-In-1 Drop may also be used in place of a daily cleaner as part of an appropriate chemical disinfection regimen.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this application was not referred to the Ophthalmic Devices Panel of the Medical Device Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the application substantially duplicates information previously reviewed by this panel.

On February 13, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 1, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated