SUPPLEMENTARY INFORMATION: On November 23, 1994, Bartels Prognostics, Inc., Issaquah, WA 98027, submitted to CDRH an application for premarket approval of Bartels ChemoResponse Assay. The device is an in vitro diagnostic device intended for use to determine resistance to 5-Fluorouracil (5–FU) of cells isolated from breast tumors and is indicated for use to assist physicians in determining if 5–FU is an ineffective treatment for relapsed breast cancer patients.

On May 1, 1995, the Microbiology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On August 1, 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 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 January 16, 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: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–31934 Filed 12–16–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0350]

Roche Molecular Systems, Inc.; Premarket Approval of Roche Amplicor HIV–1 Monitor 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 Roche Amplicor HIV–1 Monitor Test. After reviewing the recommendation of the Blood Products Advisory Committee (BPAC), FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of June 3, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 16, 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: Sukza Hwangbo, Center for Biologics Evaluation and Research (HFM–380), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3524.

SUPPLEMENTARY INFORMATION: On November 3, 1995, Roche Molecular Systems, Inc., Summerville, NJ 08876–3771, submitted to CBER an application for premarket approval of the Roche Amplicor HIV–1 Monitor Test. The device is intended to quantitate human immunodeficiency virus Type 1 (HIV–1) ribonucleic acid (RNA) in human plasma and is to be used in conjunction with clinical presentation and other laboratory markers as an indicator of HIV–1 disease prognosis. The Amplicor HIV–1 Monitor Test is based on the following processes: (1) Reverse transcriptase (RT) of target HIV–1 RNA to generate complimentary deoxyribonucleic acid (cDNA); (2) polymerase chain reaction (PCR) amplification of target cDNA; (3) hybridization of PCR amplified cDNA to specific oligonucleotide probes; and (4) detection of the probe-cDNA complex by colorimetric means. The device is not intended to be used as a HIV–1 screening test, or as a diagnostic test to confirm the presence of HIV infection.

On March 21, 1996, the premarket approval application (PMA) was referred to BPAC, an FDA advisory committee, for its recommendation regarding the use of the Amplicor HIV–1 Monitor Test to assist in disease prognosis, monitoring therapy, and patient management. From data presented by FDA, BPAC determined the test to be capable of precise and accurate measurement of HIV–1 RNA in samples of human plasma. BPAC recommended that the Amplicor HIV–1 Monitor Test was acceptable for use in the prognosis of HIV disease in specific populations, e.g., patients with CD4 positive cells of a predefined level. BPAC stated that they viewed therapy monitoring and patient management as being closely related, nonseparable issues and that sufficient clinical studies had not been performed to demonstrate the utility of the Amplicor HIV–1 Monitor Test for such uses. BPAC recommended that further postmarket surveillance studies could be conducted to determine whether the Amplicor HIV–1 Monitor Test could be validated for uses other than prognosis, i.e., therapy monitoring and patient management. CBER considered the BPAC recommendations and opinions when conducting its review of the PMA for the Amplicor HIV–1 Monitor Test. On June 3, 1996, CBER approved the application by a letter to the applicant from the Director, Office of Blood Research and Review, CBER.

The June 3, 1996, application approval letter restated postapproval conditions previously agreed to by Roche Molecular Systems, Inc., in a May 31, 1996, letter to FDA, whereby Roche Molecular Systems, Inc., will: (1) Perform postapproval studies to correlate measurements made with the Amplicor HIV–1 Monitor Test with

clinical endpoints; (2) train laboratory personnel in the use of the Amplicor HIV–1 Monitor Test at Roche Diagnostics corporate headquarters training facility and at customers' facilities to include discussions of the basic principles of PCR nucleic acid amplification, the design and maintenance of a nucleic acid amplification laboratory, management of workflow, equipment maintenance, and trouble shooting techniques; (3) provide the agency with lot release test results for the first three commercial lots of the Amplicor HIV–1 Monitor Test, submit lot release data for every third lot for a period of 12 months postapproval, and comply with agency determinations regarding the need for submissions of lot release data beyond the 1-year postapproval period; and (4) develop and provide physician and patient educational materials to include information on HIV infection, acquired immune deficiency syndrome (AIDS), anti-viral treatment modalities, viral load testing, the Amplicor HIV–1 Monitor Test, and a statement that the clinical significance of HIV–1 RNA measurements has not been fully established and that studies are in progress to determine the role of HIV RNA measurements.

A summary of the safety and effectiveness data on which CBER 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 CBER's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CBER's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (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 January 16, 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 Biologics Evaluation and Research (21 CFR 5.53).

Dated: November 26, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–31935 Filed 12–16–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–38]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Rural Health Clinics, 42 CFR 491.9 Subpart A; *Form No.:* HCFA–R–38; *Use:* This information is needed to determine if rural health clinics meet the requirements for approval for Medicare participation. *Frequency:* Other (Initial application for Medicare); *Affected Public:* Individuals or Households; Business or other for profit; Not for profit institutions; Farms; Federal Government; and State, Local or Tribal Government; *Number of Respondents:* 3,076; *Total Annual Hours:* 10,642.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Date: December 9, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 96–31907 Filed 12–16–96; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the