Overview of Health Care Industry
Overview of Hazards
Development of Occupational Safety and Health Programs
  Administrative support
  Employee involvement
  Health and safety committee
  Multidisciplinary team approach
  Medical surveillance program
  Rehabilitation
  Legal and ethical considerations
  Americans with Disabilities Act (ADA)
  Worksite analysis
  Literature review
  Identification of hazard categories
  Worksite survey
  Hazard analysis
  Exposure monitoring (biological and environmental)
  Safety and health training
  Program review and evaluation
  Development of emergency plans
Hazards
  Hazardous agents
  Biological agents
  Chemical agents
  Disinfectants and sterilants
  Antibiotics
  Hormones
  Antineoplastics
  Waste anesthetic gases
  Latex (allergy)
  Aerosolized medications (e.g., ribavirin)
  Hazardous waste
  Physical hazards
  Compressed gases and chemicals (toxic, reactive, corrosive, or flammable properties)
  Extreme temperatures (e.g., burns caused by cryogenic compounds such as dry ice or liquid nitrogen, or burns caused by the use of autoclaves or incinerators for sterilization)
  Mechanical (e.g., lacerations, punctures, and abrasions)
  Electrical
  Radiation (ionizing and nonionizing)
  Noise
  Violence
  Slips and falls
  Ergonomic hazards
  Lifting (strains or back injuries)
  Standing (for long periods of time)
  Poor lighting (eye strain)
  Psychological hazards
  Job specialization
  Discrimination
  Ergonomic factors
  Technological changes
  Work schedules (e.g., shift work, leave policies)
  Downsizing
  Violence
  Staff/patient ratios and occupational mix

Each of the major hazard categories identified above will be divided into the following subsections:

a. Explanation of the hazard

b. Occupations at risk

c. Locations in the health care facility where the hazard may occur

d. Discussion of relevant regulations

e. Discussion of controls that are specific for the hazard that will not otherwise be covered in the general control technology chapter

f. Additional resources (e.g., relevant literature, World Wide Web (www) sites).

Control Technology—General

Directory of Occupational Safety and Health Information for Health Care Workers

Appendices

a. Publications relevant to controlling infectious agents in the health care environment

b. Occupational hazards by location

c. Chemicals encountered in selected health care occupations

d. Annotated bibliography

Index

II. Issues

The draft outline provided above assumes that each chapter or section of the updated document will be developed by an expert in the area. Many of these experts will come from CDC but outside experts will also be utilized. To ensure that the information in the document is appropriate and reaches the target audiences, there are several issues which should be considered by commentors:

a. The 1988 Guidelines discussed only hazards associated with hospitals (not other health care settings such as nursing homes or drug treatment centers). It is assumed that information that is relevant for hospitals is also relevant for other health care facilities. The issue is whether information (e.g., reports of hazards) about health care facilities other than hospitals should be included in the revised guidelines, if available.

b. The draft format is based on the type of hazard (e.g., physical, ergonomic, and chemical). The issue is whether this is the best approach or if another format (e.g., presenting hazards by job task or occupation) would be better. Another issue involving the format structure is whether suggested chapters should be deleted or additional chapters included.

c. The development of small documents for different health care settings (e.g., biomedical laboratory, nursing home, home care, etc.) or occupations (e.g., nursing aids, radiological technicians, pharmacists) would be useful. The issue is whether or not these smaller documents should be done in place of one larger, all inclusive document as outlined above or in addition to this document.

d. The potential users of the health care worker guidelines include occupational physicians, administrators of health care facilities, nurses, engineers, nursing aides, safety professionals, industrial hygienists, and safety and health committees. The issue is whether the language and content should be targeted to specific occupations.

e. Information and recommendations applicable to controlling hazards in the health care industry change on a regular basis. There are a number of mechanisms that can be utilized to update this information such as providing ''updates'' on a website (e.g., as a subsection of the Institute's www site on the internet) and/or providing the information on a CD-ROM that is updated on a regular basis. The issue is what is the best mechanism(s) for reaching each intended audience(s).

Dated: December 2, 1996.

William E. Halperin,

Acting Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC)

[FR Doc. 96–31949 Filed 12–16–96; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 96M–0471]

Bartels Prognostics, Inc.; Premarket Approval of Bartels ChemoResponse Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bartels Prognostics, Inc., Issaquah, WA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Bartels ChemoResponse Assay. After reviewing the recommendation of the Microbiology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 1, 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: Sharon L. Hansen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

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