show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Mikart Inc. (Mikart) submitted a citizen petition dated February 27, 1996 (Docket No. 96P–0083/CP1), under 21 CFR 10.30(b) and 314.122(a), requesting that the agency determine whether acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, is the subject of approved ANDA 85–363 held by KV Pharmaceuticals (KV). KV obtained approval of the ANDA on August 23, 1977, but has never marketed the product. FDA has determined, for purposes of §§ 314.161 and 314.162(c), that never marketing an approved drug product is equivalent to withdrawing the drug for sale.

FDA has reviewed its records and, under § § 314.161 and 314.162(c), has determined that acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, was not withdrawn from sale for reasons of safety or effectiveness and will continue to list acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, may be approved by the agency.

Dated: July 2, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–17472 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0201]

BARD Diagnostic Sciences, Inc.; Premarket Approval of BARD® BTA® Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by BARD Diagnostic Sciences, Inc., Redmond, WA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BARD® BTA® Test. After reviewing the recommendation of the Immunology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 9, 1996.

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: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On June 6, 1994, BARD Diagnostic Sciences, Inc., Redmond, WA 98052, submitted to CDRH an application for premarket approval of BARD® BTA® Test. The BARD® BTA® rapid latex agglutination test is an in vitro device intended for the qualitative measurement of Bladder Tumor Associated Analytes in human urine to aid in the management of bladder cancer patients.

On September 21, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On November 29, 1995, 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 part 12 (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 § 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 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 August 9, 1996, 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: April 9, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–17474 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0202]

Intermedics, Inc.; Premarket Approval of Res-Q™ ACD (Arrhythmia Control Device) Epicardial Patch and Non-thoracotomy Lead (NTL) Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Intermedics, Inc., Angleton, TX, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Res-Q™ ACD (Arrhythmia Control Device) Epicardial Patch and NTL Systems. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 28, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 9, 1996.

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: Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On March 17, 1994, Intermedics, Inc., Angleton, TX 77515, submitted to CDRH an application for premarket approval of Res-Q™ ACD Epicardial Patch and NTL Systems which consists of the following: Model 101–01 and 101–01R Res-Q™ implantable arrhythmia control device; model 531–30 Rx2OOO GRAPHICS program module to be used with Intermedics commercially available model 522–06 Rx2OOO GRAPHICS programmer; models 497–05, 497–06, and 497–09 right ventricular (RV) defibrillation/pacing leads; model 497–15 subcutaneous patch lead; model 49716 superior vena cava (SVC) leads; models 497–01, 497–02, 497–11, and 497–12 epicardial patch leads; models A67 and L67 commercially available CPI® epicardial patch leads; model 370–01 adapter; model 370–21 Y-adapter; model 370–04 Test Box; models 370–03 and 370–23 Patient Cables; model 370–05 Test Load; model 370–02 Accessory Kit; model 370–10 Lead Caps; and models 370–11, 370–12, 370–13, 370–14, 370–15, 370–16, 370–48, and 370–49 Stylets. The device is an automatic, implantable cardioverter-defibrillator (ICD) system and is indicated for use in patients who are at high risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations: (1) Survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyrhythmia; or (2) recurrent, poorly tolerated sustained ventricular tachycardia (VT).

Note: The clinical outcome for hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.

On August 21, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, review and recommended approval of the application. On November 28, 1995, 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 (21 U.S.C. 360e(g)), for administrative review of CDRH'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 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 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 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 August 9, 1996, 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: April 9, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–17473 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.