that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of benzenesulfonic acid, 4-chloro–5-methyl–2-[[4,5-dihydro–3-methyl–5-oxo–1–(3-sulfophenyl)–1H-pyrazo–4-yl]azo], ammonium salt (C.I. Pigment Yellow 191:1) as a colorant in polymers intended for use in contact with food.

DATES: Written comments on petitioner's environmental assessment by December 19, 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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4566) has been filed by Ciba Specialty Chemicals Corp., 335 Water St., Newport, DE 19804. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of benzenesulfonic acid, 4-chloro–5-methyl–2-[[4,5-dihydro–3-methyl–5-oxo–1–(3-sulfophenyl)–1H-pyrazo–4-yl]azo], ammonium salt (C.I. Pigment Yellow 191:1) as a colorant in polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 3, 1997.

Alan M. Rulis,

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

[FR Doc. 97-30406 Filed 11–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0460]

Ventritex, Inc.; Premarket Approval of the TVL® Lead System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Ventritex, Inc., Sunnyvale, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the TVL® Lead System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 10, 1996, of the approval of the application.

DATES: Petitions for administrative review by December 19, 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: Doris J. Terry, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On June 30, 1995, Ventritex, Inc., Sunnyvale, CA 94086–6527, submitted to CDRH an application for premarket approval of the TVL® Lead System. The TVL® Lead System is indicated for use with commercially available pulse generators with which it has been tested. The TVL® Lead System is a transvenous defibrillation lead system and is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with an acute myocardial infarction or have ventricular tacharrhythmias. In addition, the TVL® Lead System can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the connected pulse generator provide therapy backup in the event that the arrhythmia accelerates.

In accordance with the provisions of section 515(c)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Advisory Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On May 10, 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 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 December 19, 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 16, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–30333 Filed 11–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Document Identifier: HCFA–R–94

Agency Information Collection Activities: Submission for OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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: Extension of a currently approved collection; *Title of Information Collection:* Medicaid Sterilization Regulations 45 CFR 96.73, 42 CFR 441 subpart F and Consent Form; *Form No.:* HCFA–R–94 OMB 0938–0481; *Use:* All Medicaid-eligible individuals seeking sterilization are required to sign the federally mandated consent form, acknowledging that they understand the benefits and risks of sterilization, and have received oral information concerning the sterilization operation from the provider. *Frequency:* Other (each time sterilization is sought); *Affected Public:* Individuals or Households; *Number of Respondents:* 112,526; *Total Annual Responses:* 112,526; *Total Annual Hours:* 140,658.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 6, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services,Information Technology Investment Management Group,Division of HCFA Enterprise Standards.

[FR Doc. 97–30368 Filed 11–18–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–200]

Agency Information Collection Activities: Submission for OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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 Request: Revision of a currently approved collection; *Title of Information Collection:* HEDIS 3.0 (Health Plan Data and Information Set), including the Health of Seniors and Consumer Assessment of Health Plans Study (CAHPS) surveys and supporting regulations 42 CFR 417.470, and 42 CFR 417.126; *Form Number:* HCFA–R–200 (OMB #0938–0701); Use: HEDIS and CAHPS will be used for 3 purposes: (1) To provide summary comparative data to the Medicare beneficiary to assist them in choosing among health plans; (2) to provide information to health plans for internal quality improvement activity; and (3) to provide HCFA, as purchaser, information useful for monitoring quality of and access to care provided by the plans; *Frequency:* Annually; *Affected Public:* Individuals or Households, non-profit and for profit HMOs which contract with HCFA to provide managed health care to Medicare beneficiaries; *Number of Respondents:* 293,834; *Total Annual Responses:* 293,834; *Total Annual Hours Requested:* 181,520.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 21, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–30369 Filed 11–18–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Drug Accountability Record; Submission of OMB Review; Comment Request

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 10, 1997, page 37069 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30-days for public comment. The National Institutes