Executive Order 12372 Review

This program is not subject to Executive Order 12372.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act Projects that involve the collection of information from 10 individuals or more and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Mail Stop E–18, 255 East Paces Ferry Road, NE., Room 314, Atlanta, GA 30305, on or before August 8, 1997.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Nealean Austin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Mail Stop E–18, 255 East Paces Ferry Road, NE., Room 314, Atlanta, GA 30305; telephone (404) 842–6803, or the Internet address: nea1@cdc.gov.

Programmatic technical assistance may be obtained from Bonnie C. Dyck, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Mail Stop K–50, Atlanta, GA 30341–3724; telephone (404) 488–5707, or the Internet address: bxd5@cdc.gov.

You may also obtain this announcement, and other CDC announcements, from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Please refer to Announcement 763 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock Number 017–001–00474–0), or Healthy People 2000 (Summary Report, Stock Number 017–001–00473–1), referenced in the **Introduction** through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325; telephone (202) 512–1800.

Dated: July 1, 1997.

Joseph R. Carter,

Acting Associate Director for Management And Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–17701 Filed 7–7–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Occupational Safety and Health Study Section; (NIOSH) Teleconference

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Task Group Session of the Safety and Occupational Health Study Section, National Institute for Occupational Safety and Health (NIOSH) teleconference meeting.

Time and Date: 1 p.m.–2:30 p.m., July 23, 1997.

Place: Teleconference originating at the NIOSH Grants Office, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888.

Status: The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463. Application(s) and/or proposal(s) and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the application(s) and/or proposal(s), the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Purpose: The Task Group Session of the Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation of the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888, telephone 304/285–5979.

Dated: July 1, 1997.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–17707 Filed 7–7–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0272]

Biocompatibles, Inc.; Premarket Approval of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its

approval of the application by Biocompatibles, Inc., Norfolk, VA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. The device is to be manufactured under an agreement with Ciba Vision Corp., Duluth, GA, which has authorized Biocompatibles, Inc., to incorporate information contained in its approved premarket approval applications (PMA's) for the Softcon E.W. (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 17, 1997, of the approval of the application.

DATES: Petitions for administrative review by August 7, 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 November 12, 1996, Biocompatibles, Inc., Norfolk, VA 23507, submitted to CDRH an application for premarket approval of Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear. The device is a soft (hydrophilic) contact lens and is indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in aphakic persons (after cataract surgery) that are myopic or hyperopic. Soft-55 EW Aphakic Lenses may be worn by persons who may exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The application includes authorization from Ciba Vision Corp., Duluth, GA 30136–1518, to incorporate information contained in its approved PMA's for Softcon E.W. (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear.

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 PMA was not referred to the Ophthalmic Devices 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 April 17, 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.

The labeling of the Soft-55 EW Aphakic (vifilcon A) Soft (Hydrophilic) Contact Lenses for Extended Wear states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

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 August 7, 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: June 17, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–17676 Filed 7–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0273]

Medtronic, Inc.; Premarket Approval of the CapSure® Epi Pacing Lead, Model 4965

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Medtronic, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CapSure® Epi Pacing Lead, Model 4965. 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 September 6, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 7, 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: Christopher M. Sloan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On July 17, 1995, Medtronic, Inc., Minneapolis, MN 55432–3576, submitted to CDRH an