

offenses against the United States, Federal felony offenses under 18 U.S.C. 2, 1001, 1341, and 371, respectively. These offenses were committed as part of the development of a new drug for which Mr. Snyder was conducting efficacy trials.

As a result of this conviction, FDA served Mr. Snyder by certified mail on May 8, 2002, a notice proposing to permanently debar Mr. Snyder from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Snyder an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)), that Mr. Snyder was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product. Mr. Snyder was provided 30 days to file objections and request a hearing. Mr. Snyder did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

## II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(A) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Harry W. Snyder, Jr., has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing finding, Mr. Harry W. Snyder, Jr., is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Snyder, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Snyder, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section

307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Snyder during his period of debarment.

Any application by Mr. Snyder for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N-0565 and sent to the Dockets Management Branch (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 2002.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 02M-0298, 02M-0299, 02M-0295, 02M-0381, 02M-0310, 02M-0348, 02M-0335, 02M-0353, 02M-0352, 02M-0336, 02M-0322, 02M-0361, 02M-0412, 02M-0409]

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

### FOR FURTHER INFORMATION CONTACT:

Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

### SUPPLEMENTARY INFORMATION:

#### I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet on FDA's home page at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2002, through September 30, 2002. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2002, THROUGH SEPTEMBER 30, 2002.

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P990017(S30)/02M-0298	Guidant Cardiac and Vascular Surgery Group.	ANCURE Aortoiliac Endograft System	April 24, 2002.
P990027(S2)/02M-0299	Bausch & Lomb Surgical, Inc.	TECHNOLAS 217A Excimer Laser System	May 17, 2002.
P870024(S43)/02M-0295	Paragon Vision Sciences.	PARAGON CRT (Paflucocon B), PARAGON CRT 100 (Paflucocon D), PARAGON QUADRA RG (Paflucocon B), and PARAGON QUADRA RG 100 (Paflucocon D).	June 13, 2002.
P010031/02M-0381	Medtronic, Inc.	INSYNC ICD Model 7272 Dual Chamber Implantable Cardioverter With Resynchronization Therapy and Model 9969 Application Software.	June 26, 2002.
P000058/02M-0310	Medtronic Sofamor Danek, Inc.	INFUSE BONE GRAFT/LT-CAGE Lumbar Tapered Fusion Device.	July 2, 2002.
P890017(S10)/02M-0348	Cordis Corp.	PALMAZ Balloon-Expandable Stent (Models P104R, P154R, P204R).	July 10, 2002.
P990018(S2)/02M-0335	Menicon Co., Ltd.	MENICON Z (Tisilfocon A) Rigid Gas Permeable Contact Lens.	July 12, 2002.
P960040(S26)/02M-0353	Guidant Corp.	VENTAK PRIZM 2 VR/DR Models 1860/1861; VENTAK PRIZM VR/DR Models 1850/1851/1855/1856; VENTAK PRIZM VR/DR HE Models 1852/1853, VENTAK Mini IV Models 1790/1793/1796; and VENTAK Mini III HE Model 1789.	July 18, 2002.
P910077(S37)/02M-0352	Guidant Corp.	VENTAK PRIZM 2 VR/DR Models 1860/1861; VENTAK PRIZM VR/DR Models 1850/1851/1855/1856; VENTAK PRIZM VR/DR HE Models 1852/1853, VENTAK Mini IV Models 1790/1793/1796; and VENTAK Mini III HE Model 1789.	July 18, 2002.
P010039/02M-0336	Siemens Medical Solutions USA, Inc.	Siemens SONOCUR Basic	July 19, 2002.
P020003/02M-0322	Mentor Corp.	Mentor Saline-Filled Testicular Prosthesis	July 19, 2002.
H010004/02M-0361	Guidant Corp.	NEUROLINK System, Including NEUROLINK Stent and Delivery Catheter and NEUROLINK Balloon Dilatation Catheter.	August 9, 2002.
P990026(S8)/02M-0412	Cygnus, Inc.	GlucocWatch G2 Biographer	August 26, 2002.
H020002/02M-0409	SMART Therapeutics, Inc.	Neuroform Microdelivery Stent System	September 11, 2002.

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: December 24, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4723-FA-12]

### Housing Counseling Program Announcement of Funding Awards for Fiscal Year 2002

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Announcement of funding awards.

**SUMMARY:** In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a SuperNOFA competition for funding of HUD-approved counseling agencies to provide counseling services. This announcement contains the names and addresses of the agencies selected for funding and the amount. Additionally, this announcement outlines various noncompetitive housing counseling awards made by the Department.

#### FOR FURTHER INFORMATION CONTACT:

Margaret Burns, Director, Program Support Division, Room 9266, Office of Single Family Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708-2121. Hearing- or speech-impaired individuals may access this number by calling the Federal Information Relay Service on 1-800-877-8339 or (202) 708-9300. (With

the exception of the “800” number, these are not toll free numbers.)

**SUPPLEMENTARY INFORMATION:** The Housing Counseling Program is authorized by section 106 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701x). HUD enters into agreement with qualified public or private nonprofit organizations to provide housing counseling services to low- and moderate-income individuals and families nationwide. The services include providing information, advice and assistance to renters, first-time homebuyers, homeowners, and senior citizens in areas such as pre-purchase counseling, financial management, property maintenance and other forms of housing assistance to improve the clients’ housing conditions and meet the responsibilities of tenancy and homeownership.

The purpose of the grant is to assist HUD-approved housing counseling agencies in providing housing counseling services to HUD-related and other clients. HUD funding of approved