

preapproval inspection of the manufacturing operations described in the PMA or PMA supplement. This draft guidance document does not address premarket notification (510(k)) submissions because a premarket inspection is not ordinarily conducted for 510(k) submissions. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by September 18, 2006.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0100.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On October 26, 2002, MDUFMA (Public Law 107-250) was signed into law. Among other things, MDUFMA authorized the collection of user fees to improve the performance and predictability of FDA's review of certain marketing applications, including PMAs. FDA, in consultation with the industry, agreed to dedicate user fees to help the agency meet various performance goals as outlined in a letter from the Secretary of Health and Human Services to Congress that accompanied the user fee legislation. One such goal included a commitment to "improve the scheduling and timeliness of preapproval inspections." User fees collected under MDUFMA will be used to help to cover the costs associated

with FDA's review of the PMA manufacturing section information and inspection of the manufacturing facility. FDA will monitor its good manufacturing practice preapproval inspection program and include this information in its annual performance report to Congress.

This draft guidance provides information on the administrative process that FDA intends to follow in its review of the quality system regulation (21 CFR part 820) information included in the manufacturing section of a PMA submission and the inspection of the manufacturing facility. The administrative process outlined in this draft guidance for the review of the PMA manufacturing section and the conduct of any related preapproval inspection should facilitate FDA's timely review of the application and improve the agency's coordination of the preapproval inspection with the applicant.

##### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. To receive "The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations" you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1566 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information

on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

##### **IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501-3520). The collections of information addressed in 21 CFR part 814 have been approved under OMB control number 0910-0231.

##### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4800-FA-22]

##### **Announcement of Funding Awards for Fiscal Year 2003; Community Development Work Study Program**

**AGENCY:** Office of the Assistant Secretary for Policy Development and Research, 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 document notifies the public of funding awards for the Fiscal Year 2003 Community

Development Work Study Program (CDWSP). The purpose of this document is to announce the names and addresses of the award winners and the amount of the awards to be used to attract economically disadvantaged and minority students to careers in community and economic development, community planning and community management, and to provide a cadre of well-qualified professionals to plan, implement, and administer local community development programs.

**FOR FURTHER INFORMATION CONTACT:**

Susan Brunson, Office of University Partnerships, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 8106, Washington, DC 20410, telephone (202) 708-3061, ext. 3852. To provide service for persons who are hearing- or speech-impaired, this number may be reached via TTY by dialing the Federal Information Relay Service on (800) 877-8399, or (202) 708-1455. (Telephone numbers, other than the two "800" numbers, are not toll free.)

**SUPPLEMENTARY INFORMATION:** The CDWSP is administered by the Office of University Partnerships under the Assistant Secretary for Policy Development and Research. The Office of University Partnerships administers HUD's ongoing grant programs to institutions of higher education and creates initiatives which colleges and universities can bring their traditional missions of teaching, research, service, and outreach to bear on the pressing local problems in their communities.

The CDWSP was enacted in the Housing and Community Development Act of 1988. (Earlier versions of the program were funded by the Community Development Block Grant Technical Assistance Program from 1982 through 1987 and the Comprehensive Planning Assistance Program from 1969 through 1981.) Eligible applicants include institutions of higher education having qualifying academic degrees, and Area-wide planning organizations and states that apply on behalf of such institutions. The CDWSP funds graduate programs only. Each participating institution of higher education is funded for a minimum of three and maximum of five students under the CDWSP. The CDWSP provides each participating student up to \$9,000 per year for a work stipend (for internship-type work in community building) and \$5,000 per year for tuition and additional support (for books and travel related to the academic program). Additionally, the CDWSP provides the participating institution of higher education with an administrative

allowance of \$1,000 per student per year.

The Catalog of Federal Domestic Assistance number for this program is 14.512.

On April 25, 2003 (68 FR 21181), HUD published a Notice of Funding Availability (NOFA) announcing the availability of \$2.981 million in FY 2003 funds for the CDWSP. The Department reviewed, evaluated and scored the applications received based on the criteria in the NOFA. As a result, HUD has funded the applications announced below, and in accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, U.S.C. 3545), the Department is publishing details concerning the recipients of funding awards, as set forth below.

**List of Awardees for Grant Assistance Under the FY 2003 Community Development Work Study Program Funding Competition, by Name, Address, Phone Number, Grant Amount and Number of Students Funded**

*New England*

1. The University of Vermont and State Agricultural College, Ms. Sarah Cooley, (802) 656-3360, Department of Community Development and Applied Economics, 340 Waterman Building, Burlington, VT 05405. Grant: \$150,000 to fund 5 students.

2. Bridgewater State College, Dr. Frances Jefferies, (508) 531-1783, Political Science Department, Maxwell Library 200, Bridgewater, MA 02325. Grant: \$150,000 to fund 5 students.

*New York/New Jersey*

3. Rutgers The State University of New Jersey, Ms. Kathe Newman, (732) 932-3133, Edward J. Bloustein School of Planning and Public Policy, Office of Research & Sponsored Program, 3 Rutgers Plaza, New Brunswick, NJ 08901. Grant: \$150,000 to fund 5 students.

*Mid-Atlantic*

4. Howard University, Dr. Arthur S. Paul, (202) 806-5567, Center for Urban Progress, 2400 6th Street, Washington, DC 20059. Grant: \$150,000 to fund 5 students.

*Southeast/Caribbean*

5. University of Alabama at Birmingham, Mr. Akhlaque Haque, (205) 934-4653, Department of Government—MPA Program, U238, 1530 3rd Avenue South, Birmingham, AL 35294. Grant: \$150,000 to fund 5 students.

6. Alabama A&M University, Dr. Constance J. Wilson, (256) 372-5425, Department of Community Planning and Urban Studies, P.O. Box 411, Normal, AL 35762. Grant: \$150,000 to fund 5 students.

7. Auburn University, Dr. Cal Clark, (334) 844-6460. Grant: \$150,000 to fund 5 students.

8. University of Florida, Dr. Kristin Larsen, (352) 392-0997, Department of Urban and Regional Planning, P.O. Box 115706, Gainesville, FL 32611. Grant: \$150,000 to fund 5 students.

9. Southern University, Dr. Valentine James, (225) 771-2043, Public Administration Unit, The Nelson Mandela School of Public Policy and Urban Affairs, P.O. 11280, Baton Rouge, LA 70823. Grant: \$150,000 to fund 5 students.

10. North Carolina Central University, Mr. Tyrone Eaton, (919) 530-7333, Department of Public Administration, 1801 Fayetteville Street, Durham, NC 27707. Grant: \$150,000 to fund 5 students.

11. East Carolina University, Mr. Carmine Scavo, (252) 328-4131, Department of Political Science, A-124 Brewster, Greenville, NC 27858. Grant: \$150,000 to fund 5 students.

12. Savannah State University, Ms. Shirley M. Geiger, (912) 303-4348, Master of Public Administration, P.O. Box 20386, Savannah, GA 31404. Grant: \$150,000 to fund 5 students.

*Midwest*

13. The University of Kansas Center for Research, Mr. John Nalbandian, (785) 864-9096, Department of Public Administration, 2385 Irving Hill Road, Lawrence, KS 66045. Grant: \$150,000 to fund 5 students.

14. Kansas State University, Dr. Larry Lawhon, (785) 532-2445, Department of Landscape/Architecture/Regional & Community Planning, 2 Fairchild Hall, Manhattan, KS 66506. Grant: \$126,500 to fund 5 students.

15. Wright State University, Ms. Catherine Crosby, (937) 775-2422, Center for Urban and Public Affairs, 3640 Colonel Glenn Highway, Dayton, OH 45435. Grant: \$150,000 to fund 5 students.

*Southwest*

16. University of Texas at El Paso, Dr. Paul C. Maxwell, (915) 747-6474, Institute for Policy and Economic Development, 500 West University Avenue, El Paso, TX 79968. Grant: \$150,000 to fund 5 students.

*Great Plains*

17. University of Oregon, Ms. Megan Smith, (541) 346-3881, Community

Service Center, 5219 University of Oregon, Eugene, OR 97403. Grant: \$150,000 to fund 5 students.

#### *Pacific/Hawaii*

18. The Regents of the University of California, Ms. Patricia Gates, (510) 642-8109, Institute of Urban & Regional Development, 336 Sproul Hall, MC 5950, Berkeley, CA 94720. Grant: \$150,000 to fund 5 students.

#### *Northwest/Alaska*

19. University of Washington, Ms. Carol Zuiches, Daniel J. Evans School of Public Affairs, 3935 University Way, NE., Seattle, WA 98195. Grant: \$150,000 to fund 5 students.

Dated: June 7, 2006.

**Darlene F. Williams,**

*Assistant Secretary for Policy Development and Research.*

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**BILLING CODE 4210-67-P**

## **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4800-FA-21]

### **Announcement of Funding Awards for Fiscal Year 2003; Community Outreach Partnership Centers**

**AGENCY:** Office of the Assistant Secretary for Policy Development and Research, 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 document notifies the public of funding awards for Fiscal Year 2003 Community Outreach Partnerships Centers (COPC). The purpose of this document is to announce the names, addresses and the amount awarded to the winners to be used to establish and operate Community Outreach Partnership Centers that will: (1) Conduct competent and qualified research and investigation on theoretical or practical problems in large and small cities; and (2) facilitate partnerships and outreach activities between institutions of higher education, local communities and local governments to address urban problems.

**FOR FURTHER INFORMATION CONTACT:** Susan Brunson, Office of University Partnerships, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 8106, Washington, DC 20410, telephone (202) 708-3061, ext. 3852. To provide service for persons who are hearing-or-speech-

impaired, this number may be reached via TTY by Dialing the Federal Information Relay Service on (800) 877-8339 or (202) 708-1455. (Telephone number, other than "800" TTY numbers are not toll free).

**SUPPLEMENTARY INFORMATION:** The Community Outreach Partnership Centers Program was enacted in the Housing and Community Development Act of 1992 (Pub. L. 102-550, approved October 28, 1992) and is administered by the Office of University Partnerships under the Assistant Secretary for Policy Development and Research. In addition to this program, the Office of University Partnerships administers HUD's ongoing grant programs to institutions of higher education as well as creates initiatives through which colleges and universities can bring their traditional missions of teaching, research, service, and outreach to bear on the pressing local problems in their communities.

The Community Outreach Partnership Centers Program provides funds for: Research activities which have practical application for solving specific problems in designated communities and neighborhoods; outreach, technical assistance and information exchange activities which are designed to address specific problems associated with housing, economic development, neighborhood revitalization, infrastructure, health care, job training, education, crime prevention, planning, and community organizing. On April 25, 2003 (68 FR 21105/21153), HUD published a Notice of Funding Availability (NOFA) announcing the availability of \$6.955 million (\$1.955 million has been set aside to fund COPC Futures Demonstration Program) in Fiscal Year 2003 for the Community Outreach Partnership Centers Program. The Department reviewed, evaluated, and scored the applications received based on the criteria in the NOFA. As a result, HUD has funded 10 applications for New Grants, 6 applications for New Directions Grants and 5 applications for Futures Demonstration Grants. New Grants, which cannot exceed \$400,000, are for institutions of higher education just beginning a COPC project. New Directions Grants, which cannot exceed \$150,000, are for institutions of higher education that are undertaking new activities or expanding into new neighborhoods. Futures Demonstration Grants, which cannot exceed \$400,000, are for schools of architecture, planning and design to focus on housing and planning problems of urban areas. These grants, with their grant amounts are identified below.

The Catalog Federal Domestic Assistance number for this program is 14.511.

In accordance with section 102(a) (4) (C) of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235, approved December 15, 1989), the Department is publishing details concerning the recipients of funding awards, as follows:

### **List of Awardees for Grant Assistance Under the FY 2003 Community Outreach Partnership Center (COPC) Communities Program; Funding Competition, by Institution, Address and Grant Amount**

#### *New England*

1. University at Massachusetts at Boston, Ms. Joan Arches, College of Public and Community Service, 100 Morrissey Boulevard, Boston, MA 02125. Grant: \$150,000.

#### *New York/New Jersey*

2. Rochester Institute of Technology, Ann Howard, College of Liberal Arts, 141 Lomb Memorial Drive, Rochester, NY 14623. Grant: \$ 399,998.

3. State University of New York College at Cortland, Dr. Craig Little, State University of New York College at Cortland, 35 State Street, P.O. Box 9, Albany, NY 12201. Grant: \$150,000.

#### *Mid-Atlantic*

4. Point Park College, Dr. Katherine Henderson, Office of the President, 201 Wood Street, Pittsburgh, PA 15222. Grant: \$398,405.

5. University of Pennsylvania, Ms. Rose Mazur, Office of Research Services, 3451 Walnut Street, Philadelphia, PA 19104. Grant: \$397,739 (Futures Demonstration Grantee).

#### *Southeast/Caribbean*

6. Winston-Salem State University, Ms. Valerie Howard, Winston-Salem State University, 601 Martin Luther King, Jr. Drive, Winston-Salem, NC 27110. Grant: \$400,000.

7. Anderson College, Dr. Bob Hanley, Office of Freshman Programs and Community Service, 316 Boulevard, Anderson, SC 29621. Grant: \$397,384.

8. Florida State University, Mr. Charles Connerly, Department of Urban and Regional Planning, 118 North Woodward, Tallahassee, FL 32306. Grant: \$399,969.

#### *Midwest*

9. Portland Community College, Kristin Watkins, Portland Community College, P.O. Box 19000, Portland, OR 97280. Grant: \$399,880.

10. Wright State University, Dr. Jennifer Subban, Center for Urban and