

February 1, 2009, through August 31, 2009) and \$601,308.00 (anticipated second 12-month supplement September 1, 2009, through August 31, 2010) to ensure ongoing clinical services to the target population.

Project Period: The current approved project period for NETPHD which will be supplemented began on September 1, 2007, and ends August 31, 2010; and its current budget period ends August 31, 2009.

Authority: This activity is under the authority of the Public Health Service Act, Section 330(e).

Catalogue of Federal Domestic Assistance Number: 93.224.

Justification for the Exception to Competition: Critical funding for Primary Health Care services to the population of Smith County, Texas, will be continued through a non-competitive award to Community Health Clinics of Northeast Texas as a new recipient. This non-competitive award is made because the previous grant recipient (NETPHD) serving this population notified HRSA that they would relinquish the grant and its responsibility to CHCNET. CHCNET has been responsible for the clinical operations of the program and will continue to operate the previously approved scope of project without significant changes in the organizational structure. This non-competitive replacement award will permit the new recipient to maintain the service delivery program and will ensure continuity of services. The initial supplemental funding will provide support for 7 months. Based on satisfactory performance, continued need, and availability of funds, a second and final supplemental award for these services will be awarded for 12 months. Further funding beyond August 31, 2010, for this service area will be competitively awarded during the next PHS Section 330 Health Center Program competing application process. The next available PHS Section 330 Health Center Program open competing cycle will occur in fiscal year 2009.

FOR FURTHER INFORMATION CONTACT: Monica Toomer, Chief, Southwest Branch, Central Mid-Atlantic Division, Bureau of Primary Health Care, Health Services and Resources Administration, 5600 Fishers Lane, Rockville, MD 20857; phone 301-594-4434; Monica.Toomer@hrsa.hhs.gov.

Dated: June 18, 2009.

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

The Essentials of Medical Device Regulations: A Primer for Manufacturers and Importers; Public Seminar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public seminar.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health and Office of Regulatory Affairs, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a series of three public seminars on FDA medical device regulations.

These 2-day public seminars, which are designed to address the training needs of startup and small device manufacturers and their suppliers, will include both industry and FDA perspectives and a question and answer period.

DATES: For the dates of the public seminars, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For the locations of the public seminars, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For FDA:

William Sutton, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, 10903 New Hampshire Ave., W066-4626, Silver Spring, MD 20993-0002, 301-796-5849, FAX: 301-847-8149, e-mail: William.Sutton@fda.hhs.gov.

For AdvaMed:

For hotel and general information: Veronica Allen, 202-434-7231, vallen@advamed.org.

For registration information: Katia Kunze, 202-434-7237, FAX: 202-783-8750, kkunze@advamed.org

SUPPLEMENTARY INFORMATION:

I. Background

The "Essentials of Medical Device Regulations: A Primer for Manufacturers and Importers" seminar helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating new entrepreneurs on the essentials of FDA device regulations. FDA has made education of the medical device community a high priority to assure the quality of products reaching the marketplace and to increase the rate of voluntary industry compliance with regulations.

The seminar helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise.

The seminar also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed at small businesses.

The following topics, as well as others, will be discussed at the seminar:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- Overview of the quality system regulation;
- Design controls;
- Documents, records, and change control;
- Purchasing controls and acceptance activities;
- Production and process control;
- Corrective and preventive actions;
- Complaints, medical device reports, corrections, and recalls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—Where do you go for assistance?
- General question and answer session;
- Manufacturers and suppliers—The chain regulatory responsibility;
- Reimbursement of medical technology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

II. Public Seminar Locations and Dates

The locations and dates for the public seminars are listed in table 1 of this document.

TABLE 1.—SEMINAR LOCATIONS AND DATES

Seminar Location	Date
Coronado Island Marriott Resort and Spa, 2000 Second St., Coronado, CA 92118. Details are posted on AdvaMed's Web site at www.advamedmtli.org/san_diego ¹	July 14 and 15, 2009
Gaylord Opryland Resort, 2802 Opryland Dr., Nashville, TN 37214. Details are posted on AdvaMed's Web site at www.advamedmtli.org/nashville ¹	August 4 and 5, 2009
San Juan Marriott Resort and Stellaris Casino, 1309 Ashford Ave., San Juan, PR 00907. Details are posted on AdvaMed's Web site at www.advamedmtli.org/puerto_rico ¹	August 12 and 13, 2009

¹ FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

III. Registration

The registration fee is \$650 per person per seminar. The registration fee will be used to offset the expenses of hosting the conference, including meals (breakfasts and a lunch), refreshments, meeting rooms, and training materials. It also includes a networking reception on the evening of the first day of each seminar.

To register and pay by personal check: Send your registration information (including name, title, firm name, address, telephone, and fax number) to Katia Kunze, AdvaMed, 202-434-7237, FAX: 202-783-8750, or email kkunze@advamed.org. Katia Kunze will then provide you with information on how to pay your registration fee by check.

To register and pay via the Internet: Visit the designated Web site for the seminar that you plan to attend (see table 1 of this document). Payment forms accepted are major credit card (MasterCard, Visa, or American Express).

Space is limited; therefore, interested parties are encouraged to register early. If you need special accommodations due to a disability, please contact Veronica Allen (see **FOR FURTHER INFORMATION CONTACT**) at AdvaMed at least 7 days in advance of the seminar.

Attendees are responsible for their own accommodations. For hotel information and meeting locations, see table 1 of this document. There are a limited number of hotel rooms blocked for the seminars. Please be advised that the seminar room blocks close 1 month before the beginning of the seminar. Interested parties are encouraged to make hotel reservations early, as the seminar room block will fill up quickly.

Dated: June 19, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-14907 Filed 6-23-09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, SGS North America, Inc., 1448 Texas Ave., Texas City, TX 77590, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.

DATES: The accreditation and approval of SGS North America, Inc., as commercial gauger and laboratory became effective on February 12, 2009. The next triennial inspection date will be scheduled for February 2012.

FOR FURTHER INFORMATION CONTACT:

Anthony Malana, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202-344-1060.

Dated: June 18, 2009.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E9-14915 Filed 6-23-09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, SGS North America, Inc., 4701 East Napoleon (Hwy 90), Sulfur, LA 70663, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to