SUMMARY: The Food and Drug Administration (FDA) San Francisco District, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a public workshop on FDA device regulations. This 2-day public workshop for start up and small device manufacturers and their suppliers will include both industry and FDA perspectives and a question and answer period.

Date and Time: The public workshop will be held on July 12, 2006, from 8:30 a.m. to 5:30 p.m. and July 13, 2006, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at The Marriott Fremont, 46100 Landing Pkwy., Fremont, CA 94538, 510–413–3710, FAX: 510–413–3710. For further hotel information and driving directions, go to *http://Marriott.com/property/propertypage/sjcfm*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact: *For FDA*: Eric Anderson, Office of Regulatory Affairs (HFR–PA1530), Food and Drug Administration, 96 North Third St., San Jose, CA 95115, 408–291–7548, ext. 115, FAX: 408–291–7228, e-mail: *eric.anderson@fda.hhs.gov*.

For AdvaMed: Krystine McGrath, 202–434–7237, FAX: 202–434–7850, e-mail: *kmcgrath@advamed.org*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $495.00 per person to the AdvaMed contacts (see *Contact*). The registration fee for FDA employees is waived. To register via the Internet go to *http://www.advamedmtli.org/mtli/fda.cfm*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Payment forms accepted are major credit cards (MasterCard, Visa, or American Express) or company check. If you wish to pay by check, contact Krystine McGrath (see *Contact*). For more information on the meeting, or for questions on registration, contact Krystine McGrath (see *Contact*). Attendees are responsible for their own accommodations.

The registration fee will be used to offset the expenses of hosting the workshop, including meals (breakfasts and lunches), refreshments, meeting rooms, and training materials. It also includes a networking reception on July 12, 2006. Space is limited; therefore, interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Eric Anderson (see *Contact*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''Essentials of FDA Device Regulations: A Primer for Manufacturers and Suppliers'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating new entrepreneurs on 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 workshop 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 workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- The quality system regulations and inspections;
- Design controls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—where do you go for assistance;
- Manufacturers and suppliers—the chain of regulatory responsibility;
- Reimbursement and medical technology;
- The AdvaMed code of ethics;
- Fraud and abuse;
- Human factors;
- Documents, records and change controls;
- Purchasing controls and acceptance activities;
- Production and process control;
- Corrective and preventive actions;
- Complaint handling, medical device reporting, and servicing; and
- Training and audits;

Transcripts: There will be no transcripts for this public workshop.

Dated: June 16, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–5570 Filed 6–16–06; 4:02 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0369]

Guidance for Industry; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.'' The guidance provides recommendations to developers of new plant varieties, including bioengineered plant varieties, on the early food safety evaluation of new non-pesticidal proteins. The guidance describes procedures for submitting an early food safety evaluation of such proteins to the agency.

DATES: This guidance document is final upon the date of publication. Submit written or electronic comments concerning the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' to the Office of Food Additive Safety (HFS–255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments concerning the 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*. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–

3835, 301–436–1165, FAX 301–436–2965, or e-mail: *mary.ditto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 2, 2002 (67 FR 50578), the U.S. Office of Science and Technology Policy (OSTP) proposed Federal actions to update field test requirements and to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and diversity of bioengineered crops. As the number and diversity of field tests for bioengineered plants increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced during field tests with commercial seeds or grain may also increase. This could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA's voluntary consultation procedures for foods derived from new plant varieties (referred to as ''biotechnology consultation'' in the case of bioengineered plants).[1] FDA is issuing this guidance document to address this possibility.

In the **Federal Register** of November 24, 2004 (69 FR 68381), FDA made available a draft guidance for industry entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' and gave interested parties an opportunity to submit comments by January 24, 2005. The agency considered received comments as it finalized this guidance.

This guidance describes the procedure for early food safety evaluation of new proteins produced by new plant varieties that are under development for food use, including, for example, such proteins produced in bioengineered plants. This guidance also provides information to sponsors and developers about submitting their evaluation to FDA.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). This guidance represents FDA's current thinking on the early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**). If you cannot identify the appropriate FDA staff, call the telephone number listed in the title page of the guidance.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the guidance was approved under OMB Control No. 0910–0583.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. 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. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at either *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/cvm/Guidance/published.htm*.

Dated: June 14, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9688 Filed 6–20–06; 8:45 am]

BILLING CODE 4160–01–S

[1] ''Guidance on Consultation Procedures: Foods Derived from New Plant Varieties'' can be found at *http://www.cfsan.fda.gov/~lrd/consulpr.html*.

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Agency Information Collection Activities: Petroleum Refineries in Foreign Trade Subzones

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

ACTION: Proposed collection; comments requested.

SUMMARY: Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Petroleum Refineries in Foreign Trade. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (71 FR 12383–12384) on March 10, 2006, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before July 21, 2006.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget Desk Officer at *Nathan.Lesser@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the Proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of