decomposition. 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 statutes and regulations.

II. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs home page. It may be accessed at *http://www.fda.gov/ora* under ''Compliance Reference.''

Dated: June 30, 2008.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–16453 Filed 7–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Animal Models for the Treatment of Acute Radiation Syndrome; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, and the National Institutes of Health, National Institute of Allergy and Infectious Diseases, are announcing a public workshop entitled ''Animal Models for the Treatment of Acute Radiation Syndrome (ARS).'' The purpose of the public workshop is to discuss issues that should be considered when developing animal models to assist in developing and demonstrating the efficacy of products intended for treatment of ARS.

Date and Time: The public workshop will be held on September 17, 2008, from 8:30 a.m. to 5:30 p.m., and on September 18, 2008, from 8:30 a.m. to 1 p.m.

Location: The public workshop will be held at the Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079; e-mail: *CBERTraining@fda.hhs.gov* (Subject line: Animal Models for ARS Workshop).

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 25, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m. If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: There are no approved medical products with an indication for treatment of ARS. The public workshop will provide the opportunity to explore current research involving animal models for the development of treatments for ARS, and to determine what areas need further research. There will be feature presentations by experts from government, academia, and medicine. The first day of the workshop will include presentations on the effects of radiation and the management of patients with ARS, and a discussion of the application of the animal rule to therapies for ARS. Both days of the workshop will examine the challenges faced when using animal models to mimic radiation exposure scenarios and will include panel discussions that will focus on various animal models and their application to the different syndromes of ARS.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16461 Filed 7–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Rapid Methods for Detecting Mycoplasma Contamination in the Manufacture of Vaccines, Including Pandemic Influenza Vaccines, and Other Biological Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Rapid Methods for Detecting Mycoplasma Contamination in the Manufacture of Vaccines, Including Pandemic Influenza Vaccines, and Other Biological Products.'' The purpose of the public workshop is to provide a forum on recent scientific and technical achievements in the development of rapid methods for mycoplasma testing during the manufacture of vaccines and other biological products. Such discussion may help to assess how these methods compare with currently used methods. Expedited manufacture may be of particular importance to public health during an influenza pandemic.

Date and Time: The public workshop will be held on September 22, 2008, from 8:30 a.m. to 5 p.m., and September 23, 2008, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, e-mail: *CBERTraining@fda.hhs.gov* (Subject line: Mycoplasma Workshop).

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 22, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

Submit written abstracts to the contact person by August 15, 2008 (see section II of this document for additional information).

SUPPLEMENTARY INFORMATION:

I. Background

FDA will explore the use of alternative methods for detecting mycoplasma contamination in the manufacture of vaccines, including pandemic influenza vaccines, and other biological products. Alternative methods that allow detection of mycoplasma in a shorter period, as compared to the current methods, could expedite the manufacture of vaccines and other biological products. The workshop is aimed at: (1) Identifying promising rapid method(s) for further validation to demonstrate equivalency or superiority to methods currently used for mycoplasma testing during the manufacture of vaccines and other biological products and (2) providing information that may lead to collaborative studies with FDA on testing for mycoplasma. The program agenda will be available at *http://www.fda.gov/cber/scireg.htm*, by September 5, 2008.

II. Submission of the Abstracts

For purposes of discussion at the workshop, FDA is requesting submission of abstracts that describe current developments in rapid methods for detection of mycoplasma contamination during manufacture of vaccines and other biological products. FDA will select a limited number of abstracts for formal presentation at the workshop by the abstract authors. If time permits, FDA may allow additional presentations from interested persons attending the meeting who did not submit an abstract. FDA will notify authors of abstracts accepted for presentation at the workshop by August 25, 2008.

Abstracts should be a maximum of 350 words, printed (typewritten or computer) and double-spaced. The title should be brief and capitalized. The authors name(s), contact information, and agency, institution, or facility involved should be listed. The author who intends to present the abstract should submit a current curriculum vitae with the abstract.

Dated: July 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16459 Filed 7–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1995–N–0400 (formerly Docket No. 1995N–0245), FDA–1995–N–0029 (formerly Docket No. 1995N–0282), FDA–1995–N–0224 (formerly Docket No. 1995N–0347)]

Small Entity Compliance Guide: Food Labeling; Nutrient Content Claims: Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of September 23, 1997, entitled ''Food Labeling; Nutrient Content Claims; Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods.'' This SECG is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to *http://www.regulations.gov*. Submit written requests for single copies of the SECG to the Division of Dietary Supplement Programs, Office of Nutrition, Labeling, and Dietary Supplements (HFS–810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–2639. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1997 (62 FR 49868), FDA issued a final rule amending its regulations to: Define the term ''high potency'' as a nutrient content claim; define nutrient content claims using the term ''antioxidant'' (e.g., ''good source of antioxidants,'' ''high in antioxidants,'' ''more antioxidants'') and to correct an omission pertaining to the use of ''sugar free'' claims on dietary supplements. This final rule became effective March 23, 1999.[1]

FDA examined the economic implementation of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–602) and determined that the final rule might have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the requirements of the regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on this subject. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this SECG. 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 SECG and received

[1] FDA published a correction to the final rule in the **Federal Register** of October 24, 1997 (62 FR 55331). The correction was to correct a RIN number that appeared in the September 23, 1997, final rule.