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 topic. 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. The SECG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: April 24, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9870 Filed 4–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0198]

Small Entity Compliance Guide: Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives—Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is being issued for a final rule published in the **Federal Register** of January 5, 2009, and it 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 requests for single copies of the SECG to the Division of Petition Review, Office of Food Additive Safety (HFS–265), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or FAX your request to 301–436–2972. Send one self-addressed adhesive label to assist that office in processing your request. 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1303.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 5, 2009 (74 FR 207), FDA issued a final rule requiring the declaration of cochineal extract and carmine by name on the label of all foods and cosmetic products that contain these color additives. This final rule becomes effective January 5, 2011.

FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule may 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 legal requirements of the January 5, 2009, final rule set forth in 21 CFR parts 73 and 101 concerning cochineal extract and carmine.

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

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: April 24, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9868 Filed 4–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Director, National Institutes of Health (NIH), the authorities added to the Public Health Service Act by Section 801 of Public Law 110–85, the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j), as amended, pertaining to the expansion of the Clinical Trial Registry and Results Data Bank described therein. Specifically, the Director is delegated the following authorities:

1. 402(j)(2)(A)(ii)(IV), 42 U.S.C. 282(j)(2)(A)(ii)(IV): The Secretary may make publicly available certain administrative data collected for the registry, as necessary.

2. 402(j)(3)(A)(i), 42 U.S.C. 282(j)(3)(A)(i): To ensure that the Data Bank includes links to results information for those trials that form the primary basis for an efficacy claim or are performed after clearance or approval of the drug or device, under 42 U.S.C. 282(j)(3)(A)(i).

3. 402(j)(3)(A)(ii)(I), 42 U.S.C. 282(j)(3)(A)(ii)(I): To ensure that the Data Bank includes links to specified FDA information.