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.

4. 402(j)(3)(A)(ii)(II), 42 U.S.C. 282(j)(3)(A)(ii)(II): To ensure that the Data Bank includes links to specified NIH information.

5. 402(j)(3)(A)(ii)(iii), 42 U.S.C. 282(j)(3)(A)(ii)(iii): To include links to the FDA and NIH information described above for Data Bank entries for clinical trials submitted to the Data Bank prior to the enactment of FDAAA.

6. 402(j)(3)(C), 42 U.S.C. 282(j)(3)(C): To include in the Data Bank the specified ''basic results'' information for drugs that are approved under section 505 of the Federal Food, Drug and Cosmetic Act or licensed under section 351 of the Public Health Service Act, and for devices that are cleared under section 510(k) of the Federal Food, Drug and Cosmetic Act, or approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act.

7. 402(j)(3)(D)(vi), 42 U.S.C. 282(j)(3)(D)(vi): To consider the status of World Health Organization consensus data elements for reporting clinical trial results when issuing regulations.

8. 402(j)(3)(D)(vii), 42 U.S.C. 282(j)(3)(D)(vii): To hold a public meeting to provide an opportunity for input from interested parties with regard to the regulations to be issued pursuant to 42 U.S.C. 282(j)(3)(D)(i).

9. 402(j)(3)(I)(iii), 42 U.S.C. 282(j)(3)(I)(iii): To include in the Data Bank tables of information of anticipated and unanticipated serious adverse events and anticipated and unanticipated frequent adverse events, upon the application of 42 U.S.C. 282(j)(3)(I)(ii).

10. 402(j)(3)(I)(iv), 42 U.S.C. 282(j)(I)(iv): To consult with experts in risk communication and post, with the tables described in 42 U.S.C. 282(j)(3)(I)(iii), information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

11. 402(j)(4)(B)(i), 42 U.S.C. 282(j)(B)(i): To determine for a specified clinical trial, that posting in the Data Bank of clinical trial information for such clinical trial is necessary to protect the public health, and further, to require by notification that such information be submitted to, and accepted on behalf of the Secretary by, the Director of the National Institutes of Health, in accord with 42 U.S.C. 282(j)(4)(B)(i)(I).

12. 402(j)(5)(A)(iv), 42 U.S.C. 282(j)(5)(A)(iv): To consult with other agencies that conduct human subjects research in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulation), to determine if such research is an applicable clinical trial and develop, with such agencies, procedures to ensure the submission of clinical trial information.

13. 402(j)(5)(C)(i), 42 U.S.C. 282(j)(5)(C)(i): To use the publicly available information and any other information available to the Secretary about applicable clinical trials to verify the accuracy of submitted results information for the Pilot Quality Control Study.

This delegation will be exercised in accordance with the Department's applicable policies, procedures, guidelines and regulations.

I ratify and affirm any actions taken by you or your subordinates that involved the exercise of the authorities delegated herein prior to the effective date of this delegation. This delegation is effective upon date of signature.

Dated: April 21, 2009.

Charles E. Johnson,

Acting Secretary.

[FR Doc. E9–9699 Filed 4–29–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Reservation Roads

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission of information collection to the Office of Management and Budget.

SUMMARY: The Bureau of Indian Affairs (BIA) is submitting the information collection for the Indian Reservation Roads (IRR) Program, OMB Control No. 1076–0161, to the Office of Management and Budget for renewal. The current approval period is approaching expiration; this renewal will allow us to continue to operate the IRR program. This renewal is necessary for tribal participation in the IRR Program and for the allocation of funding for the IRR Program to federally recognized tribal governments for transportation assistance.

DATE: Submit comments on or before June 1, 2009.

ADDRESSES: Submit comments on the information collection to the Desk Officer for the Department of the Interior at the Office of Management and Budget, by fax at (202) 395–5806 or e-mail at *OIRA_DOCKET@omb.eop.gov*. Please send copy of your comments to: LeRoy Gishi, Chief, Division of Transportation, 1849 C Street, NW. MS 4512 MIB, Washington, DC 20240, fax: (202) 208–4696.

FOR FURTHER INFORMATION CONTACT: You may request further information or obtain copies of the proposed information collection request from LeRoy Gishi, Chief, Division of Transportation, telephone (202) 513–7711.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection is necessary to allow Federally recognized tribal governments to participate in the IRR Program as defined in 23 U.S.C. 204(a)(1). Some of the information collected determines the allocation of IRR program funds to Indian tribes as described in 23 U.S.C. 202(d)(2)(A).

II. Summary of Public Comments Received

The BIA received comments from one commenter in response to the notice published January 12, 2009 (74 FR 1244), which announced that we would submit this renewal to OMB for approval and provided the 60-day public comment period. The commenter had a number of suggestions that would be appropriate for consideration upon amending the rule; however, because the scope of this public comment period is limited to the information collections, the BIA was not able to accommodate these requests. Comments specific to the information collection included the following. The commenter expressed concern that the word ''some'' in the Brief Description indicated that there were other information collections that BIA did not address. The Brief Description addresses all the information collections associated with Indian Reservation Roads—the word ''some'' indicates that some of these information collections are required to obtain or maintain a benefit (program participation and funding) and others are voluntary. Another comment asked why an applicant must provide documentation that the project meets the definition of an IRR transportation facility and is on the IRR inventory when the information already exists. The BIA requires this information as part of the IRR High Priority Project application because the application is a collection of all information necessary for the Department to make an approval determination based upon criteria established by law. The commenter also stated that they believe that the amount of information could be reduced. The information collection was developed by meetings between tribal members and the BIA. What emerged was a list that met the various needs of the tribe and the requirements of the law which