FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB Control Numbers 0910–0014 and 0910–0001, respectively.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: April 22, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10005 Filed 4–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2303–N]

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Establishment of the Children's Health Insurance Program Working Group and Request for Nominations for Members

AGENCIES: Centers for Medicare & Medicaid Services (CMS), HHS; Employee Benefits Security Administration (EBSA), DOL

ACTION: Notice.

SUMMARY: This notice announces the establishment of the Children's Health Insurance Program Working Group and discusses the group's purpose and charter. It also solicits nominations for members.

DATES: Nominations for membership will be considered if they are received by June 1, 2009.

ADDRESSES: Send nominations and written requests for copies of the Charter of the Children's Health Insurance Program Working Group to—Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Mail stop: S2–06–28, Attention: Stacey Green.

Web page: You may also review the charter online at: *http://www.cms.hhs.gov/FACA/06_CHIPWorkingGroup.asp.*

FOR FURTHER INFORMATION CONTACT: Stacey Green, Centers for Medicare & Medicaid Services, HHS at *Stacey.Green@cms.hhs.gov* or (410) 786–6102; or Amy Turner, Employee Benefits Security Administration, DOL at (202) 693–8335. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

Section 311(b)(1)(C) of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3) (Feb. 4, 2009), directs the Secretary of Health and Human Services and the Secretary of Labor to jointly establish a Medicaid, CHIP, and Employer-Sponsored Coverage Coordination Working Group (''the CHIP Working Group''). The CHIP Working Group, as chartered, under the legal authority of section 311(b)(1)(C) of CHIPRA (Pub. L. 111–3), is also governed by the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.

II. Charter, General Responsibilities, and Composition of the Children's Health Insurance Program Working Group

A. Charter Information and General Responsibilities

On April 3, 2009 the Secretary of Health and Human Services and the Secretary of Labor signed the charter establishing the CHIP Working Group. This group will meet up to 3 times over the life of the Group and will terminate 17 months from the charter filing date. You may obtain a copy of the charter for the CHIP Working Group by mailing a written request to the address specified in the *ADDRESSES* section of this notice. The purpose of the Working Group shall be to:

- Develop a model coverage coordination disclosure form for plan administrators of group health plans to complete for purposes of permitting a State to determine the availability and cost-effectiveness of coverage available under group health plans to employees who have family members who are eligible for premium assistance offered under a State plan under titles XIX or XXI of the Social Security Act (the Act) and to allow for coordination of coverage for enrollees of such plans. The form shall provide the following information in addition to other information as the Working Group determines appropriate: (1) A determination of whether the employee is eligible for coverage under the group health plan, (2) the name and contact information of the plan administrator of the group health plan, (3) the benefits offered under the plan, (4) the premiums and cost-sharing required under the plan, and (5) any other information relevant to the coverage under the plan.
- Identify the impediments to the effective coordination of coverage available to families that include employees of employers that maintain group health plans and members who are eligible for medical assistance under title XIX of the Act or child health assistance or other health benefits coverage under title XXI of the Act.
- Not later than August 5, 2010, submit to the Secretary of Labor and the Secretary of Health and Human Services the model disclosure form as stated above along with a report containing recommendations for appropriate measures for addressing the impediments (as stated above) to the effective coordination of coverage between group health plans and the State plans under titles XIX and XXI of the Act.

B. Composition of the CHIP Working Group

The Working Group shall consist of not more than 30 members, jointly appointed by the Secretary of Health and Human Services and the Secretary of Labor, including the chair(s), one of whom shall be appointed by the Secretary of Health and Human Services and one of whom shall be appointed by the Secretary of Labor. Members will serve without compensation but will receive reimbursement for travel costs.

The Working Group shall be composed of representatives of: The Department of Labor; the Department of

Health and Human Services; State directors of the Medicaid Program under title XIX of the Act; State directors of the State Children's Health Insurance Program under title XXI of the Act; employers, including owners of small businesses and their trade or industry representatives and certified human resource and payroll professionals; plan administrators and plan sponsors of group health plans as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, as amended; health insurance issuers; and children and other beneficiaries of medical assistance under title XIX of the Act or child health assistance or other health benefits coverage under title XXI of the Act.

III. Submission of Nominations

The Department of Labor and the Department of Health and Human Services (the Departments) are requesting nominations for membership on the CHIP Working Group. The Departments will consider qualified individuals who are self-nominated or are nominated by organizations representing affected stakeholders when selecting those representatives. The Departments will make every effort to appoint members to serve on the advisory board from among those candidates determined to meet specific statutory categories and Departmental needs and in a manner to ensure an appropriate balance of membership. The Secretaries, however, reserve the discretion to appoint members to serve on the advisory board in response to this notice if necessary to meet specific statutory categories and Departmental needs in a manner to ensure an appropriate balance of membership.

Any interested person may nominate one or more qualified individuals (self-nominations will also be accepted) for each of the categories listed in section II.B of this notice. Each nomination must include the following information:

1. A letter of nomination that contains contact information for both the nominator and nominee (if not the same).

2. A statement from the nominee that he or she is willing to serve on the Working Group for its duration and an explanation of interest in serving on the advisory board. The nominee should also indicate which category or categories he or she is willing to represent and whether he or she would be willing to serve as the chair of the advisory board. (For self-nominations, this information may be included in the nomination letter.)

3. A curriculum vitae that indicates the nominee's educational and/or experience with Medicaid, CHIP, or experience with employment-based health coverage.

4. Two letters of reference that support the nominee's qualifications for participation on the advisory board. (For nominations other than self-nominations, a nomination letter that includes information supporting the nominee's qualifications may be counted as one of the letters of reference.)

To ensure that a nomination is considered, the Departments must receive all of the nomination information specified in section III of this notice by June 1, 2009. Nominations should be mailed to the address specified in the **ADDRESSES** section of this notice.

Authority: Section 311(b)(1)(C) of the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3) (Feb. 4, 2009). The Children's Health Insurance Program (CHIP) Working Group is governed by the provisions of the Federal Advisory Committee Act, (Pub. L. 92–463) (Oct. 6, 1972), as amended, 5 U.S.C. App.

Dated: April 10, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services, Department of Health and Human Services.

Dated: April 28, 2009.

Alan D. Lebowitz,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

[FR Doc. E9–10083 Filed 4–30–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0597]

Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed; 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 #195 entitled ''Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed'' This small entities compliance guide aids renderers in complying with the requirements of the final rule published in the **Federal Register** of April 25, 2008 (73 FR 22720). FDA's goal is to strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle and to reduce the risk of human exposure to the BSE agent.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shannon Jordre, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9229, *Shannon.jordre@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 26, 2008 (73 FR 72062), FDA published the notice of availability for a draft guidance entitled ''Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed'' giving interested persons until January 26, 2009, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. FDA received a number of comments that were outside the scope of the draft guidance, and thus those comments were not addressed in the final version.

The comments raised a number of questions including the following:

- Inquiries from an industry organization regarding the difference between cattle materials prohibited in animal feed (CMPAF) and specified risk materials (SRM);
- Industry requests for clarification on the provisions of the regulation concerning insoluble impurity standards for tallow and how to achieve compliance;
- Whether a certificate of analysis is necessary for each shipment of tallow;
- Whether edible tallow must meet the 0.15 percent insoluble impurities