

Management between 9 a.m. and 4 p.m., Monday through Friday.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

William J. Burkholder, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-402-

5900; email: [William.Burkholder@fda.hhs.gov](mailto:William.Burkholder@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of September 10, 2012 (77 FR 55480), FDA published the notice of availability for a draft CPG entitled “Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats” giving interested persons until November 9, 2012, to comment on the draft CPG. FDA received several comments on the draft CPG and those comments were considered as the CPG was finalized.

FDA revised the title of the final CPG. The final CPG is entitled “Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases.” In addition to revising the title, editorial changes were made to improve clarity.

The CPG announced in this notice finalizes the draft CPG dated September 10, 2012.

**II. Significance of Guidance**

This level 1 CPG is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on labeling and marketing of dog and cat food diets intended to diagnose, cure, mitigate, treat, or prevent diseases. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. In the **Federal Register** of September 10, 2012 (77 FR 55480), FDA published a notice announcing the availability of the draft CPG. This document contained a Paperwork Reduction Act burden analysis and requested comments on a proposed collection of information (77 FR 55480 at 55481). We have concluded that our guidance to FDA staff with respect to factors to consider when

determining whether to take regulatory action against an article of dog or cat food does not impose collection of information burdens on the public. In addition, to the extent that we obtain information during an enforcement action, this collection is exempt from OMB review under 44 U.S.C. 3518(c)(1)(B) and 5 CFR 1320.4(a)(2) as collection of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened, for example, as part of the decision to detain a drug or an article of food.

**IV. Electronic Access**

Persons with access to the Internet may obtain the CPG at either <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm> under “Compliance Policy Guides” or <http://www.regulations.gov>.

Dated: April 25, 2016.

**Katherine Bent,**

*Assistant Commissioner for Compliance Policy.*

[FR Doc. 2016–10234 Filed 4–29–16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Assistant Secretary for Health**

[Document Identifier: HHS-OS-0990-New-60D]

**Agency Information Collection Activities; Proposed Collection; Public Comment Request**

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OASH seeks comments from the public

regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before July 1, 2016.

**ADDRESSES:** Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690-6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS-OS-0990-New-60D for reference.

Information Collection Request Title: Evaluation of the *Second Decade Project* Community Planning Guide Abstract: The Office of the Assistant Secretary for Health (OASH) is requesting approval from the Office of Management and Budget (OMB) for an evaluation of the *Second Decade Project* Community Planning Guide.

OASH has a long history of collaborating with communities to improve adolescent health outcomes. To further help communities build an environment that promotes adolescent health, OASH recently developed Promoting Health and Healthy Development in the Second Decade of Life: A Planning Guide for Communities ("the Guide"). The purpose of the Guide is to provide an easy to follow tool that community leaders can use to (1) establish a community coalition with

broad membership, and (2) develop a community plan for improving adolescent health and well-being that includes multi-impact strategies. To understand whether and how community leaders are able to use the Guide to achieve these two goals, OASH needs information about the Guide's utility and effectiveness. The evaluation of the Second Decade Project Community Planning Guide ("the evaluation") is intended to support the goals of OASH's Second Decade Project of helping community leaders incorporate the needs of children, adolescents and young adults in community growth and development plans, and to improve outcomes of young adults and adolescents. Five communities will participate in the piloting and evaluation of the Guide. The evaluation will provide OASH with critical information regarding the components of the Guide that community leaders found most useful and effective in accomplishing their goals of improving adolescent health and wellbeing; the compilation and inclusiveness of the coalitions implementing the Guide; and the demographic and environmental context of these communities. While secondary data will be collected from sources such as the U.S. Census Bureau American Community Survey and Youth Risk Behavior and National Health Interview Surveys, these sources do not provide nuanced information needed by OASH

to understand the contexts in which the Guide is most effective.

**Likely Respondents—Qualitative data** will be collected through semi-structured telephone interviews and through focus groups. Telephone interviews will be conducted with community leaders (Community Leader Interview) in the five pilot sites to explore how the use of the Guide supported key leaders in their development of a diverse coalition and educating the community about issues facing adolescents. Focus groups will be conducted with coalition members (Coalition Member Focus Groups) from the five pilot sites to assess how the Guide facilitated the work of the coalition to develop a comprehensive community plan that addresses critically important adolescent health issues.

**Quantitative data** will be collected through Web-based surveys with coalition members from the five communities and with secondary stakeholders—specifically, adolescent health experts and state/local health department officials—selected by OASH. The Coalition Assessment Survey will assess coalition members' perspectives on the usefulness and ease of implementing the Guide. The Secondary Stakeholder Survey will engage Adolescent Health researchers and practitioners to garner additional feedback and assessment of the Guide.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Community Leader Interview (CLI) .....	50	1	1	50
Coalition Member Focus Group (CFG) .....	80	1	1	80
Coalition Assessment Survey (CAS) .....	250	1	.25	63
Secondary Stakeholder Survey (SSS) .....	50	1	.5	25
<b>Total</b> .....	<b>430</b>	.....	.....	<b>218</b>

OASH specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

**Terry S. Clark,**

*Asst. Information Collection Clearance Officer.*

[FR Doc. 2016-10199 Filed 4-29-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Solicitation of Nominations for Membership on the National Vaccine Advisory Committee**

**AGENCY:** National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**AUTHORITY:** 42 U.S.C. 300aa-5, Section 2105 of the Public Health Service (PHS) Act, as amended. The National Vaccine