

Total Annual Responses: 12,810; Total Annual Hours: 3,618,703. (For policy questions regarding this collection contact Samone Angel at 410-786-1123.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; **Title of Information Collection:** Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; **Use:** In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called "items," that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB-LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various populations: Elders (65 years and older); younger adults (18-64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and

conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants. **Form Number:** CMS-10243 (OMB control number: 0938-1037); **Frequency:** On occasion; **Affected Public:** Individuals and households; **Number of Respondents:** 5,650; **Total Annual Responses:** 5,650; **Total Annual Hours:** 2,825. (For policy questions regarding this collection contact Allison Weaver at 410-786-4924.)

Dated: April 27, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0755]

Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended To Diagnose, Cure, Mitigate, Treat, or Prevent Diseases; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) 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." This CPG provides guidance to FDA staff on issues related to dog and cat diets that are labeled and/or marketed as intending to diagnose, cure, mitigate, treat, or prevent diseases and to provide all or most nutrients in support of meeting the animal's total daily nutrient requirements. This CPG finalizes the 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," dated September 10, 2012.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted as confidential, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0755 for "Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets

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.

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.

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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