12. Disclosure of Lobbying Activities, if applicable.

13. Copy of approved indirect cost rate agreement, if applicable.

14. Documentation of current OMB A–133 required financial audit, if applicable.

Evaluation criteria for review of the application will be comprised of three principal areas:

a. Program information which includes current organizational capabilities and operations.

b. Program planning and evaluation which includes identification of measurable goals, products, personnel and workplanning.

c. Program reporting which includes organizational capabilities and qualifications and categorical budget and justification.

Authority: Section 1110 of the Social Security Act, codified at 42 U.S.C. 1310.

Dated: August 16, 2012.

Daniel F. Kane,

Chief Grants Management Officer, Office of Acquisition and Grants Management, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–22189 Filed 9–7–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0755]

Draft Compliance Policy Guide Sec. 690.150 on Labeling and Marketing of Nutritional Products Intended for Use To Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (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.'' This draft CPG is intended to provide guidance to FDA staff and industry on how FDA intends to use its enforcement discretion with regard to the labeling and marketing of dog and cat food products that are labeled and/or marketed as intending to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support of meeting the animal's total daily nutrient requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by November 9, 2012.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Director, Division of Compliance Policy, Office of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., rm. 4044, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–827–0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG. Submit electronic comments to *http://www.regulations.gov*.

Submit written comments on the draft CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William J. Burkholder, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6865, *William.Burkholder@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft CPG entitled ''Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats.'' The purpose of this CPG is to communicate FDA's strategy for enforcing the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to dog and cat food products that make labeling or marketing claims to diagnose, cure, mitigate, treat, or prevent disease. Since 1988, the Center for Veterinary Medicine (CVM) has observed an increase in the number of dog and cat food products making such claims that are sold with, or without, the direction of a licensed veterinarian. Because of this increase, and to help ensure animal safety, CVM is issuing this draft CPG to set out its current thinking with respect to factors it will consider before determining whether to take regulatory action against dog and cat food products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

FDA does not generally intend to recommend or initiate regulatory actions against dog and cat food products that are labeled and/or marketed as intended for use to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support of meeting the animal's total daily nutrient requirements when all the following factors are present. Specifically: (1) Manufacturers make the products available to the public only through licensed veterinarians or through retail or Internet sales to individuals purchasing the product under the direction of a veterinarian; (2) manufacturers do not market such products as alternatives to approved new animal drugs; (3) the manufacturer is registered under section 415 of the FD&C Act (21 U.S.C. 350(d)); (4) manufacturers comply with all food labeling requirements for such products (see 21 CFR part 501); (5) manufacturers do not include indications for a disease claim (e.g., obesity, renal failure) on the label of such products; (6) manufacturers limit distribution of material with any disease claims for such products only to veterinary professionals; (7) manufacturers secure electronic resources for the dissemination of labeling information and promotional materials such that they are available only to veterinary professionals; (8) manufacturers include only ingredients that are general regarded as safe (GRAS) ingredients, approved food additives, or feed ingredients defined in the 2012 *Official Publication* of the Association of American Feed Control Officials (AAFCO) for the intended uses in such products; [1] and (9) the label and labeling for such products are not false and misleading in other respects.[2]

II. Significance of Guidance

This level 1 draft CPG is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent 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

[1] Although food containing these unapproved food additives is adulterated within the meaning of section 402(a)(2)(c)(i), FDA is unlikely to initiate enforcement action solely on this basis if the food additive in question is included in the 2012 edition of the *Official Publication* of AAFCO. As part of its efforts to work with State partners, FDA has reviewed safety information related to many of these listed products, and those listed in the 2012 *Official Publication* generally do not fall within our current enforcement priorities.

[2] A therapeutic claim that is not scientifically substantiated would be considered false or misleading, thus making the product misbranded.

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. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing a notice of the proposed collection of information set forth below.

With respect to the following collection of information, we invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Compliance Policy Guide on Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats.

Description: The purpose of this CPG is to communicate FDA's strategy with respect to dog and cat food products that are labeled and/or marketed as intending to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support of meeting the animal's total daily nutrient requirements.

Description of Respondents: Manufacturers of dog and cat foods that are labeled and/or marketed as intending to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support of meeting the animal's total daily nutrient requirements.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 402 and 403 of the FD&C Act	5	75	375	.25	94

[1] There are no operating costs or maintenance costs associated with this collection of information.

CVM estimates from its experience that approximately 5 manufacturers will be affected by the draft CPG, times 75 products produced annually equals 375 total annual responses. The hours per response are based on approximately .25 hour per response for respondents to look up the ingredient names in the AFFCO *Official Publication*.

This draft CPG also refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 571 (Food Additive Petitions and FAP Labeling) have been approved under OMB control number 0910–0546. The collection of information in 21 CFR 570.35 (GRAS) has been approved under OMB control number 0910–0342. The requirement for food facility registration has been approved under OMB control number 0910–0502.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. It is only necessary to send one set of comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Copies of the CPG may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home pages include this draft CPG and may be accessed at *http://www.fda.gov/ICECI/ComplianceManuals/* under ''Compliance Policy Guides.''

Dated: August 24, 2012.

Dara A. Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2012–22231 Filed 9–7–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0902]

Withdrawal of Approval of New Animal Drug Applications; Chorionic Gonadotropin; Naloxone; Oxymorphone; Oxytocin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs) at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective September 20, 2012.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6843, email: *david.alterman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The sponsors in table 1 of this document have requested that FDA withdraw approval of the four NADAs listed