can contact the reporting PETNet member.

In the **Federal Register** of July 27, 2010 (75 FR 43990), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 12 comments on the 60-day notice, 11 from private citizens and one from a veterinary association. None of the comments addressed paperwork issues. Ten of the comments generally supported the PETNet concept, while two comments generally did not support it.

Several comments suggested that it be mandatory, rather than voluntary, for all 50 States to participate in PETNet. FDA declines to follow the comments' suggestion, but we note that invitations have been sent to all 50 States requesting their participation in PETNet, and at this time 35 States have responded that they will participate in the program.

Several comments stated that the information in PETNet should be publicly available and not just available to Federal and State pet food regulators. FDA disagrees with this comment. Much of the information shared through PETNet will be preliminary reports of potential pet food problems that turn out to be false or to otherwise have no public health significance. FDA and State Agencies routinely receive these types of reports and followup on them without notifying the public. FDA believes that State and Federal regulators can decide how to best use the information in PETNet, including how to use their resources to determine if a pet food incident warranting public notification exists.

One comment recommended that FDA "closely assess reported incidents as soon as possible to ensure no confounding factors bias any determination of a need for a pet food recall." To assist in this effort, the comment recommended that FDA incorporate drop down menus in the PETNet reporting form to collect information about whether the adverse event was confirmed (versus suspected) to have been caused by pet food, if the exposure was acute or chronic, and the clinical outcome of the case.

PETNet will be an additional information resource used by FDA, but will not change FDA's current process for determining the need for pet food recalls. The information the American Veterinary Medical Association recommends FDA collect will be considered by pet food regulatory professional in deciding whether to enter a report into PETNet. Some of the recommended information may also be derived from the current PETNet form. For example, question 11 asks if the reporter has laboratory results available to share. Laboratory results are key factors in confirming whether an adverse event is caused by a pet food. Answers to question 8 will provide an indication about duration of exposure, and some clinical outcomes can be derived form question 6.

One comment stated that the focus of PETNet is wrong and that the U.S. Department of Agriculture (USDA) should be involved because it is their responsibility to inspect pet food plants. FDA notes that it is FDA, not USDA that is responsible for ensuring the safety of pet food, and that FDA conducts inspections of pet food manufacturing establishments. However, USDA is a Federal Agency that can contribute to PETNet and USDA has been invited/will participate in PETNet. Another comment stated that PETNet "lacks data security" and is a "needlessly invasive project" whose object to "identify tainted doggie food" is of questionable value. With respect to data security, the data shared through PETNet is contained on a database limited to State and Federal Government officials, and the data collection form has been designed such that it is highly unlikely to contain confidential or trade secret information that requires additional data protection measures. Additionally, the Agency disagrees that the project is invasive since it is just a method of sharing existing information among State and Federal regulators. Finally, the objective of the project is to protect animal health is valid and consistent with FDA's mission.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 342 & 343/Section 1002(b) of the 2007 FDA amendments act/form FDA	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Form FDA 3756	50	10	500	20/60	167

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

FDA estimates that each State will report (*i.e.,* fill out the PETNet form to alert other PETNet members about a pet food-related incident) approximately 10 times per year. This estimate represents the maximum number of reports that FDA expects a State to submit in a year, and in many cases the number of reports submitted by a State will probably be far less. FDA believes that, given the form only has 11 items and most are drop down fields, 20 minutes is a sufficient amount of time to complete the form. State regulatory officials responsible for pet food already possess computer systems and have the Internet access necessary to participate in PETNet, and thus there are no capital expenditures associated with the reporting.

Regarding recordkeeping, State regulatory officials who report on PETNet receive the reportable information from consumers in their States in the course of their customary and regular duties. Further, these individuals already maintain records of such consumer complaints in the course of their duties which are sufficient for the purposes of reporting on PETNet. Therefore, FDA believes that the proposed collection of information does not have additional recordkeeping requirements.

Dated: December 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–32275 Filed 12–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0466]

Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase

Activity (the CPG). The CPG provides guidance for FDA staff on its enforcement policies for pathogens and other indicators of inadequate pasteurization or post-pasteurization contamination of dairy products.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the 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: Monica Metz, Center for Food Safety and Applied Nutrition (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 2009 (74 FR 62795), FDA made available draft CPG Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity and gave interested parties an opportunity to submit comments by February 1, 2010. The agency reviewed and evaluated these comments and has modified the CPG where appropriate.

The CPG provides guidance for FDA staff regarding pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. The CPG outlines regulatory enforcement policies for FDA staff to use to initiate legal action recommendations based on analytical determinations that a dairy product contains a pathogenic microorganism (*i.e., Salmonella* species, enterohemorrhagic *Escherichia coli* (EHEC) O157:H7 and other enterohemorrhagic *Escherichia coli, Campylobacter jejuni, Yersinia enterocolitica,* or *Clostridium botulinum*); toxins produced by *Clostridium botulinum,* enterotoxigenic *Staphylococcus,* or *Bacillus cereus; Staphylococcus aureus; Bacillus cereus;* nontoxigenic *Escherichia coli;* or alkaline phosphatase. The CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing the CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents FDA's current thinking on pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate 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**) either electronic or written comments regarding the CPG. It is only necessary to submit one set of comments. It is no longer necessary to send two paper copies of mailed comments. Identify comments 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.

III. Electronic Access

Persons with access to the Internet may obtain the CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at *http://www.fda.gov/ora/compliance_ref/cpg/default.htm.*

Dated: December 16, 2010.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–32232 Filed 12–22–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0298] (Formerly Docket No. 2004D–0499)

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice To Extend Expiration Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of expiration date.

SUMMARY: The Food and Drug Administration (FDA) is extending the expiration date of compliance policy guide (CPG) Sec. 400.210 entitled "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs" to December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of the Commissioner, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2004 (69 FR 67360), FDA announced the availability of CPG Sec. 400.210 entitled "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs." Previous extensions of the expiration date of the CPG were published in 2007 and 2008 (72 FR 65750, November 23, 2007; 73 FR 78371, December 22, 2008). FDA has identified RFID as a promising technology to be used in the various efforts to combat counterfeit drugs. The CPG describes how the Agency intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs. The goal of the CPG is to facilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the U.S. drug supply.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. Section 913 of FDAAA addressed pharmaceutical safety and created section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355e). Section 505D(b) of the FD&C Act requires the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) of the FD&C Act states that these new standards shall address promising technologies, which may include RFID technology.

In implementing section 505D of the FD&C Act, FDA is currently addressing issues, such as promising technologies, that are relevant also for the CPG. In addition, FDA is considering further the experience of stakeholders and the Agency under the CPG. As we consider all of these issues, the CPG will remain in effect until December 31, 2012.

Dated: December 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–32274 Filed 12–22–10; 8:45 am]

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