electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product CERENIA TABLETS (maropitant citrate monohydrate). CERENIA TABLETS is indicated for the prevention of acute vomiting in dogs and the prevention of vomiting due to motion sickness in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CERENIA TABLETS (U.S. Patent No. 6,255,320) from Pfizer Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 6, 2008, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of CERENIA TABLETS represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CERENIA TABLETS is 1,887 days. Of this time, 1,841 days occurred during the testing phase of the regulatory review period, while 46 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective*: December 1, 2001. The applicant claims November 21, 2000, as the date the investigational new animal drug application (INAD) became effective. However, the date that a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, is the effective date for the INAD. According to FDA records, December 1, 2001, is the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the Federal Food, Drug, and Cosmetic Act*: December 15, 2006. The applicant claims December 13, 2006, as the date the new animal drug application (NADA) for CERENIA TABLETS (NADA 141–262) was initially submitted. However, a review of FDA records reveals that NADA 141–262 was initially submitted on December 15, 2006.

3. *The date the application was approved*: January 29, 2007. FDA has verified the applicant's claim that NADA 141–262 was approved on January 29, 2007.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 267 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 11, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 8, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 17, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–5109 Filed 3–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0060]

Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient.'' This guidance is intended to clarify for manufacturers who produce foods containing a peanut-derived product as an ingredient that there is a risk that *Salmonella* species may be present in the incoming peanut-derived product, and to recommend measures to address that risk.

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

ADDRESSES: 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 on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock,Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Guidance for Industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient.'' This guidance is intended to clarify for manufacturers who produce foods containing a peanut-derived product as an ingredient that there is a risk that *Salmonella* species (spp.) may be present in the incoming peanut-derived product, and to recommend measures to address that risk. Peanut-derived products include peanuts, peanut butter, peanut paste, peanut meal, and peanut granules.

In the recent past, products made from peanuts have been associated with two large, multi-state *Salmonella* outbreaks. The first of these, an outbreak of *Salmonella* Tennessee in 2007 linked to peanut butter, resulted in more than 600 illnesses in 47 states (Ref. 1). More recently, peanut butter and peanut paste have been confirmed as the source of a large multi-state outbreak caused by *Salmonella* Typhimurium (Ref. 2). Peanut-derived products that have been recalled have been used as ingredients in other products such as cookies, crackers, cereal, candy, and ice cream. This had led to additional recalls.

FDA is issuing this guidance as a level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the current circumstances. The guidance represents the agency's current thinking on measures to address the risk for contamination by *Salmonella* spp. in foods containing a peanut-derived product as an ingredient. 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**) 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.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.cfsan.fda.gov/guidance.html*.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter; Product May be Contaminated With *Salmonella*, FDA News, P07–21, available at *http://www.fda.gov/bbs/topics/NEWS/2007/NEW01563.html*, February 14, 2007.

2. FDA, Recall of Products Containing Peanut Butter; *Salmonella* Typhimurium, available at *http://www.fda.gov/oc/opacom/hottopics/salmonellatyph.html*, updated February 4, 2009.

Dated: March 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5367 Filed 3–9–09; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program Patient Data Collection Form—[New]

The purpose of the Patient Navigator Outreach and Chronic Disease Prevention (PN) Demonstration Program is to promote model ''patient navigator'' programs to improve health care outcomes for individuals with cancer and/or other chronic diseases, with a specific emphasis on health disparity populations. This program aims to coordinate comprehensive health services for patients in need of chronic disease care and management through enhanced chronic disease management provided by patient navigators.

In order to describe successful PN program models and make recommendations on the ability of such programs to improve patient outcomes, data is needed at the individual patient, patient navigator, and PN program levels. This information includes:

■ Sociodemographics of patients (*e.g.*, insurance status, income, education level, gender, age, race and ethnicity, primary language, number of family dependents) served;

■ Patient access barriers to standard chronic disease care (*e.g.*, access to pharmaceuticals, distance of patient's home from health care facilities utilized, primary mode of transportation to health care facilities utilized, cultural and linguistic barriers as well as literacy levels);

■ Health care service utilization (*e.g.*, screening rates, compliance rate for appointments and follow-up exams,