

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.

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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,

time interval between diagnosis or referral and resolution date);

■ Patient health status (e.g., type and stage of diagnosis, chronic disease status, final outcome or result); and

■ Patient navigation data (e.g., type of navigator, patient navigation training plans and outcomes, point at which patient navigator was brought into the process, number of patients referred,

how patient barriers were resolved, patient satisfaction, follow-up outcomes—such as number of uninsured who get health coverage).

This information will be collected from patients or their designated caregiver, patient navigators, and PN program administrators. Maintaining confidentiality of patient medical information is a concern and thus all

personal information will be de-identified to protect the confidentiality of all patients. Data collection and disclosure processes will abide by Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule provisions and procedures.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient ¹ Data Intake Form	6000	1	6000	0.5	3000
SubTotal—Patient Burden	6000	1	6000	0.5	3000
Patient Navigator Survey	30	1	30	0.25	7.5
Patient Navigator Encounter/Tracking Log ²	30	750	22,500	0.25	5625
SubTotal—Patient Navigator Burden	30	751	22530	0.5	5632.5
Grantee PN Administrative Records ³	6	1	6	0.5	3
Medical Record and Clinic Data ⁴ (Baseline Measures)	6	2000	12000	2	24000
Quarterly Report	6	4	24	1	24
SubTotal—Grantee Burden	18	2005	12030	3.5	24027
Total Average Annual Burden	6048	2757	40560	4.5	32659.5

¹ Estimated number of navigated patients per year based on applications was rounded to 6000. See table below for projected numbers navigated by Grantee.

² Assumes 5 log entries of PN activities per patient.

³ Includes administrative data related to PN recruitment, hiring, and training.

⁴ Includes medical record abstraction and clinic database abstraction on individual patients (note: Decreased to 2 hours per patient).

	Over 2 yrs	Annual
Goodwin	400	200
Lutheran	650	325
Northeast	6000	3000
Palmetto	3000	1500
South Broward ..	2200	1100
Texas Tech	500	250
Total	12750	6375

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: February 27, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-5102 Filed 3-10-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Revision of OMB No. 0925-0001/exp. 11/30/10, Research and Research Training Grant Applications and Related Forms

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 10, 2008, page 75121 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after November 30, 2010, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Research and Research Training Grant Applications and Related Forms. **Type of Information Collection Request:** Revision, OMB 0925-0001, Expiration

Date 11/30/2010. **Form Numbers:** PHS 398, 2590, 2271, 3734 and HHS 568.

Need and Use of Information Collection:

The application is used by applicants to request Federal assistance for research and research-related training. The other related forms are used for trainee appointment, final invention reporting, and to relinquish rights to a research grant. **Frequency of response:**

Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed.

Affected Public: Individuals or Households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. **Type of Respondents:**

Adult scientific professionals. The annual reporting burden is as follows: **Estimated Number of Respondents:** 160,135; **Estimated Number of Responses per Respondent:** 1; **Average Burden Hours Per Response:** 14; and **Estimated Total Annual Burden Hours Requested:** 2,251,500. The estimated annualized cost to respondents is \$78,802,500.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;