Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle—21 CFR 189.5 and 700.27 (OMB Control Number 0910–0623—Extension)

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(a)) provides requirements with regard to imported food and cosmetics and provides for refusal of admission into the United States of human food and cosmetics that appear to be adulterated. Section 701(b) of the FD&C Act (21 U.S.C. 371(b)) authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act. To address the potential risk of BSE in human food and cosmetics, FDA regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) designate certain materials from cattle as "prohibited cattle materials," including specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) (Beef). Under the regulations no human food or cosmetic may be manufactured from, processed with, or otherwise contain prohibited cattle materials. However, the Agency may designate a country from which cattle materials inspected and passed for human consumption are not considered prohibited cattle materials and their use does not render a human food or cosmetic adulterated.

Sections 189.5(e) and 700.27(e) provide that a country seeking to be so designated must send a written request to the Director, Center for Food Safety and Applied Nutrition (CFSAN). The information the country is required to submit includes information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other information relevant to determining whether specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, or MS (Beef) from the country seeking designation should be considered prohibited cattle materials. FDA uses the information to determine whether to grant a request for designation, and whether to impose conditions if a request is granted.

Sections 189.5 and 700.27 further state that countries that have been designated under §§ 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate. Therefore, designated countries may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. FDA uses the information to ensure that their designation remains appropriate.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 189.5 and 700.27— request for designation	1	1	1	80	80
§§ 189.5(e) and 700.27(e)—response to request for review by FDA	1	1	1	26	26
Total					106

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

This estimate is based on FDA's experience and the average number of requests for designation under §§ 189.5 and 700.27 received in the past 3 years. FDA received one request for designation in 2009 and one in 2010. Based on this experience, FDA estimates the annual number of new requests for designation will be 1. FDA estimates that preparing the information required by §§ 189.5 and 700.27 and submitting it to the Agency in the form of a written request to the Director, CFSAN will require a burden of approximately 80 hours per request. Thus, the annual burden for new requests for designation is estimated to be 80 hours, as shown in table 1, row 1 of this document.

Under §§ 189.5(e) and 700.27(e), designated countries are subject to future review by FDA and may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. In the last 3 years, FDA has not requested any reviews. Thus, the Agency estimates that one or fewer will occur annually in the future. We estimate that the designated country undergoing a review in the future will need one third the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours (80 hours x 0.33 = 26.4 hours, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 2 of this document. The total annual burden for this information collection is estimated to be 106 hours.

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9154 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0263]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on "Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak."

DATES: Submit either electronic or written comments on the collection of information by June 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under 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(c) 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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.

Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak—(OMB Control Number 0910—NEW)

This proposed collection of information entitled "Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak" will be conducted under a cooperative agreement between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Risk Communication Research (CRCR) at the University of Maryland. JIFSAN was established in 1996 and is a public and private partnership between FDA and the University of Maryland. The CRCR will design and administer the study.

FDA is requesting OMB approval under the PRA for the CRCR to conduct research with produce growers, food retailers, and consumers to gain information about these groups' risk perceptions associated with produce that has recently been subject to a food recall resulting from a foodborne illness outbreak. The purpose of this research is to help FDA better understand whether the magnitude and duration of the decline in commodity consumption following food recalls can be partly explained by grower and retailer speculations and projections about consumers' attitudes toward food recalls resulting from foodborne illness outbreaks. This research will be used to assess how grower, retailer, and consumer perceptions, attitudes, knowledge, and beliefs affect market recovery after a hypothetical fresh spinach recall.

Epidemiologists define foodborne illness outbreaks as two or more cases of a similar illness resulting from the ingestion of a common food (Ref. 1). Because many foodborne illness cases are mild, most outbreaks are never recognized or brought to the attention of public health authorities. When the outbreaks are large in scale or cause hospitalization, serious illness, or death, public health officials will inform the public in order to try to stop the spread of disease. A food recall can occur when a particular food in the marketplace is found to have a known contaminant, because either people have become sickened by it or pathogen testing has revealed contamination (Ref. 2). The purpose of a food recall is to rid retail establishments of the product and to inform consumers that they should discard the product if they have it in their homes. Although the purpose of a food recall is to keep consumers from becoming ill, food recalls can be costly to all sectors of the food distribution chain (Ref. 3). The goal of the proposed project is to test, by experimental study, whether the psychological tendency called "attribution error," contributes to unnecessarily prolonging the economic effects of a food recall. "Attribution error" is the tendency people have of overestimating others' negative response to situations compared to their own response. If industry decisionmakers' measures of consumer response are biased by "attribution error," industry could be contributing to its own slow recovery after a food recall.

When a widespread foodborne illness outbreak results in a food recall, the product can be out of the marketplace for an extended period of time; this occurred when fresh, bagged spinach was recalled in 2006 (Ref. 3). Tomatoes were also less available following the *Salmonella* Saintpaul outbreak in 2008 (Ref. 4). Although growers and retailers want to provide safe foods, decisions surrounding production, wholesale, and retail sales forecasting in response to a food recall affects how quickly the food is again available for consumption. We hypothesize that industry's over-attribution of consumers' fear of the food after such a food recall would result in the food being kept off of the market longer than necessary.

The CRCR plans to conduct an experiment using a Web-based questionnaire. The center will use a convenience sample of 900 participants (180 growers, 180 retailers, 540 consumers) drawn from industry networks (for the growers and retailers), and a Web-based panel of U.S. households (for the consumers). Participation in the study is voluntary.

This study will help FDA better understand the reasons for the time between a food recall resulting from a foodborne illness outbreak and market recovery. In order to understand the complexities of market recovery process, the CRCR will compare understandings and reactions of growers, retailers, and consumers to a hypothetical food recall resulting from a hypothetical foodborne illness outbreak. To make this comparison, individuals in each group will be assigned to one of the following experimental conditions (consisting of vignettes in the form of news articles on a hypothetical food recall): An "anger" scenario, a "fear" scenario, or a "control" scenario. After

reading the news article, participants will complete a questionnaire assessing their emotional response, appraisals, attribution of responsibility, perceptions about the safety of the affected produce, intentions to grow, sell, or buy the affected produce, perceived probability of a repeat event, and a measure of their innate ability to effectively respond to the information in the article.

To help design and refine the questionnaire, we will recruit 25 participants in order to conduct 10 cognitive interviews. We estimate cognitive interview recruitment will take 5 minutes (0.083 hours), for a total of 2 hours. The cognitive interviews are estimated at 1 hour per response for a total of 10 hours for the cognitive interview activities. We expect to send screeners to 800 members of a consumer panel, each taking 2 minutes (0.03 hours) to complete, for a total of 24 hours for the consumer panel screener activity. We also expect to administer 360 screeners to growers and retailers, each taking 2 minutes (0.033 hours) to complete, for a total of 24 hours (11 + 11 = 22). Twenty-four participants (20 consumers, 2 growers, 2 retailers) will complete the pre-test. Each pre-test will take 10 minutes (0.17 hours) for a total of 5 hours for the pre-test activity. We estimate that 900 individuals (540 consumers, 180 growers, and 180 retailers) will complete the questionnaire for the experiment, each taking 10 minutes (0.17 hours) for a total of 153 hours for the experimental study activities. The estimated total hour burden of the collection of information is 215 hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Cognitive Interview Recruitment	25	1	25	5/60	2
Cognitive Interviews	10	1	10	1	10
Consumer Panel Screener	800	1	800	2/60	24
Grower Screener	360	1	360	2/60	11
Retailer Screener	360	1	360	2/60	11
Pre-tests	24	1	24	10/60	5
Experiment	900	1	900	10/60	153
Total					216

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

II. References

11. Olsen, S., L. MacKinon, *et al.,* "Surveillance for Foodborne Disease Outbreaks—United States, 1993 to1997," *Morbidity and Mortality Weekly Report* 49(SS01), pp. 1 through 51, 2000.
2. FDA 101: Product Recalls—From First Alert to Effectiveness Checks, Available at *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm.*
3. Calvin, L., "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves* 5(3), pp. 24 through 31, 2007.
4. Lucier, G. and R. Dettmann, "Vegetables and Melons Outlook," A Report From the United States Department of Agriculture, Economic Research Service, VGS–327, June 26, 2008.

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9155 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0241]

Determination of Regulatory Review Period for Purposes of Patent Extension; ATRYN; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 21, 2011 (76 FR 15323). The document announced the determination of the regulatory review period for ATRYN. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993–0002, 301–796–9138.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–6509, appearing on page 15323, in the **Federal Register** of Monday, March 21, 2011, the following correction is made:

1. On page 15323, in the first column, in the Docket No. heading, "[Docket No. FDA–2010–E–0241]" is corrected to read "[Docket No. FDA–2009–E–0241]".

Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9153 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.