falsified the calcium response data in Figure 5A (right panel) of the grant application referenced above by adding ATP as a reagent to the mouse airway epithelial cells to sharpen the results purported to be caused by PGN without disclosing that ATP had been added and without disclosing that ATP was not added to the control sample.

The questioned research was not submitted for publication.

Dr. Sanyal has entered into a Voluntary Settlement Agreement with ORI and Duke, in which he voluntarily agreed to the administrative actions set forth below. The administrative actions are required for two (2) years beginning on the date of Dr. Sanyal's employment in a research position in which he receives or applies for PHS support on or after the effective date of the Agreement (September 16, 2011); however, if he has not obtained employment in a research position in which he receives or applies for PHS support within three (3) years of the effective date of the Agreement, the administrative actions set forth below will no longer apply. Dr. Sanyal has voluntarily agreed:

(1) To have his research supervised as described below and to notify his employer(s)/institutions(s) of the terms of this supervision; Respondent agrees to ensure that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS supported research, the institution employing him will submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he will not participate in any PHS supported research from the effective date of this Agreement until a plan for supervision is submitted to and approved by ORI; Respondent agrees to be responsible for maintaining compliance with the agreed upon plan for supervision;

(2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or contract involving PHS supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2011–26127 Filed 10–7–11; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–3180–N2]

Food and Drug Administration

[Docket No. FDA–2010–N–0308]

Pilot Program for Parallel Review of Medical Products

AGENCY: Food and Drug Administration, Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) (the Agencies) are soliciting nominations from sponsors of innovative device technologies to participate in a pilot program for concurrent review of certain FDA premarket review submissions and CMS national coverage determinations. The Agencies announced the intention to initiate a pilot program in the **Federal Register** of September 17, 2010. The Agencies are now providing notice of the procedures for voluntary participation in the pilot program, as well as the guiding principles the Agencies intend to follow.

DATES: *Effective Date:* November 10, 2011.

FOR FURTHER INFORMATION CONTACT:

For device sponsors interested in requesting voluntary parallel review:

Markham C. Luke, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5550, *e-mail: markham.luke@fda.hhs.gov.*

For General questions about parallel review:

Peter Beckerman, Office of Policy, Food and Drug Administration, 301–796–4830, *e-mail: peter.beckerman@fda.hhs.gov* or Tamara Syrek Jensen, Centers for Medicare and Medicaid Services, 410–786–3529, *e-mail: Tamara.Syrekjensen@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Parallel Review Proposal

As discussed in the September 17, 2010, **Federal Register** notice (75 FR 57045), parallel review is intended to reduce the time between FDA marketing approval and CMS national coverage determinations, thereby improving the quality of patient health care by facilitating earlier access to innovative medical products for Medicare beneficiaries. In the notice of September 17, 2010, we solicited comments on parallel review of submissions to FDA and CMS for regulated medical products. We also stated our intention to initiate a pilot program for parallel review of devices. The Agencies received 36 comments before the comment period closed on December 16, 2010. The public comments can be found at: *http://www.regulations.gov,* identified by docket number FDA–2010–N–0308. Major themes of the comments included, among others: Parallel review should be sponsor/requester initiated, voluntary, and include an option to opt out of a national coverage determination (NCD); agencies should clarify the confidentiality standards for data sharing between the Agencies; and agencies should establish clear and concise guidelines on the procedures and a timeline for parallel review. These comments have informed the parallel review pilot program for medical devices we are announcing in this notice. We also intend to seek input and feedback from candidate sponsor/requesters who participate in the pilot. Current information describing the FDA–CMS Parallel Review Pilot Program for Medical Devices can be found at the following Web site: *http://www.parallel-review.fda.gov.*

B. Expected Benefits of Parallel Review

The expected benefits of an FDA–CMS parallel review program were discussed in the September 17, 2010, notice. The anticipated benefits include facilitating development of innovative new products and increased efficiency in the Agencies' review processes.

It has come to our attention that innovators have generally focused solely on obtaining FDA approval, only to later realize that Medicare payment may not automatically be forthcoming.

As stated in the notice of September 17, 2010, parallel review will serve the

public interest by providing the possibility of reducing the time between FDA marketing approval or clearance decisions and Medicare NCDs. The efficiencies gained by parallel review are expected to benefit all interested parties. Patients are expected to gain quicker access to innovative medical technologies if they are covered. The sponsor/requester gains timely insight to the information needs of CMS with respect to pursuing a positive NCD as well as a potentially shortened time to payment due to a streamlined multi-review process. The Agencies gain enhanced channels of communication. Specifically with regard to CMS, its early involvement will streamline the decision making process. It will also focus attention on health outcomes of importance to Medicare, and provide early awareness of any remaining evidence gaps. If there are evidence gaps, CMS may address them by implementing coverage with evidence development (CED) or other policy vehicles. For example, if FDA approval or clearance is conditioned on a post-approval study, CMS could decide to cover the device within the parameters of the post-approval study under CED.

II. Parallel Review Pilot Program for Medical Devices

The Agencies have developed a pilot program that reflects our review of the comments received on the September 17, 2010, notice and our interest in creating a streamlined process with minimal additional burden to interested sponsor/requesters. This document outlines the: (1) Guiding principles underlying the pilot program; (2) appropriate candidates for the pilot program; (3) procedures FDA and CMS intend to follow in conducting parallel product reviews; and (4) general roles and responsibilities of the sponsor/requester, FDA, and CMS.

A. Guiding Principles

In response to comments received, the Agencies have identified basic principles underlying the parallel review pilot program described in this document. The following principles are intended to create a common understanding among the sponsor/requester, FDA, and CMS about the goals and parameters of the parallel review pilot program:

1. Participation in parallel review will not affect the review standard for device approval by FDA or for a coverage determination by CMS.

2. The Agencies will adhere to all statutory and regulatory requirements as stipulated in the memorandum of understanding between FDA and CMS, available at *http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm217585.htm.*

3. A sponsor/requester may withdraw from, and FDA and CMS may terminate, parallel review up until the time of CMS's public posting of an NCD tracking sheet.

4. The Agencies will not publicly disclose participation of a sponsor/requester in parallel review prior to CMS's posting of an NCD tracking sheet, unless the sponsor/requester consents or has already made this information public or disclosure is required by law. If a sponsor/requester does not wish the information that would be revealed by the posting of the NCD tracking sheet to become public, it must withdraw from parallel review prior to this point.

5. Due to Agency resource issues the pilot program expects to accept no more than three to five candidates per year.

B. Appropriate Candidates

During its pilot phase, the Agencies believe parallel review should focus on truly innovative technologies that are most likely to benefit from the efficiencies of parallel review. Accordingly, appropriate candidates for the parallel review pilot are medical devices which each use the following:

1. New technologies for which the sponsor/requester has had sufficient pre-investigational device exemption (IDE) interaction with FDA or approved IDE application.

2. New technologies for which an original or supplemental application for premarket approval (PMA) or petition for de novo review would be required.

3. New technologies that fall within the scope of a Part A or Part B Medicare benefit category and are not subject to an NCD.

The agencies encourage any interested sponsors who believe their devices are appropriate candidates and would like to explore the use of the pilot program to contact FDA by e-mail at: *parallel-review@fda.gov,* before initiating the procedures referenced under section II.C of this document entitled ''C. Procedures.''

C. Procedures

For sponsor/requesters of devices that have already had contact with FDA through the pre-IDE or IDE process, much of the information necessary to assess the suitability of a candidate technology should already be in FDA's possession. The Agencies have developed the following procedures to ensure adequate information to assess a candidate's suitability for parallel review without creating a burdensome new application process:

1. *Nomination.* The sponsor/requester of an innovative therapeutic or diagnostic device may nominate its device for participation in parallel review by following the instructions posted on the *http://www.parallel-review.fda.gov* web page. FDA intends to acknowledge receipt of nominations by e-mail. The following information will assist FDA in processing and responding to nominations:

- Name of the sponsor/requester and relevant contact information;
- Pre-IDE/IDE/PMA/De Novo reference number;
- Name of the product;
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat;
- Stage of development of the technology (that is, in preclinical testing, in clinical trials, currently undergoing premarket review by FDA);
- Brief statement explaining why the device is an appropriate candidate for the pilot program as described under the section II.B of this document entitled: ''B. Appropriate Candidates.''

2. *FDA/CMS Consideration.* The Agencies intend to meet to consider a nomination within 30 days of receiving a complete nomination containing the information described previously. The Agencies may contact the sponsor/requester to request supplemental information.

3. *Sponsor/requester Notification.* Upon completion of the consideration meeting, the Agencies will notify the sponsor/requester whether the product is an appropriate candidate for the parallel review pilot program.

4. *Acceptance Meeting.* If deemed an appropriate candidate, the Agencies will meet with the product sponsor/requester, either in person or by phone.

5. *FDA Review.* Parallel review candidates will be reviewed according the normal FDA review process. Participation in parallel review will not affect user fees, review timeframes or procedures, or the FDA standard of approval, which is reasonable assurance of safety and effectiveness.

6. *CMS NCD Review and Timing.* CMS will begin its informal review process sometime after submission of the PMA or de novo petition. For PMAs, this will typically begin after the PMA-specific Panel meeting of the FDA Medical Devices Advisory Committee.

D. Roles and Responsibilities

The Agencies have outlined the general roles and responsibilities of each participant in the parallel review process to ensure clarity and shared

understandings. These roles and responsibilities are as follows:

1. *Sponsor/requester.* The sponsor/requester initiates consideration for parallel review by submitting a complete nomination as outlined previously under ''1. Nomination,'' of section II.C of this document entitled ''Procedures.''. Once a nomination has been submitted, the sponsor/requester should comply with all requirements necessary for FDA review of a PMA or de novo petition and CMS issuance of an NCD including the submission of a formal request for an NCD. The Agencies request that a sponsor/requester who wishes to withdraw from the parallel review process notify the FDA and CMS in writing before CMS' formal opening of an NCD by the posting of the NCD tracking sheet.

2. *The FDA.* FDA will provide a secure and confidential nomination and review process as outlined previously in section II.C of this document. FDA will initiate review of nominations for parallel review by retrieving applications from the secure mailbox, and coordinating with CMS, on the planning and implementation of the parallel review process. FDA will review PMAs and de novo petitions for products that have been selected by the Agencies for parallel review according to the usual timeframes, procedures, and review standards for PMA approval and de novo classification.

3. *The CMS.* In addition to the coverage review, CMS's parallel review roles include participating in the nomination process as well as coordinating with FDA regarding the planning and implementation of the parallel review process. During the parallel review, CMS is responsible for maintaining open communication channels with FDA and the sponsor/requester and for fulfilling its statutory obligations concerning the NCD process.

E. Duration of the Pilot

The Agencies intend to accept requests for participation in the pilot program for parallel review for 2 years. The Agencies may terminate the pilot program before the close of the 2-year period, or may extend the pilot program beyond 2 years. The decisions will be announced in the **Federal Register.**

F. Evaluation

The Agencies intend to use their experience with the pilot program to develop a parallel review program not only for devices but also for drugs and biological products. The Agencies anticipate their experience with the parallel review program for devices and feedback from participants in the program will inform guidance for a broader program applicable to all medical products. The Agencies may also determine that they should extend or modify the parallel review pilot program to continue their evaluation.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 21, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 21, 2011.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

[FR Doc. 2011–25907 Filed 10–6–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0263]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by November 10, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak.'' Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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)

I. Background

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