

## ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Collecting saliva to measure cotinine and cortisol, and measuring height and weight .....	2890	1	0.3	867

Estimated Total Annual Burden Hours: 5,334

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address:

[OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration, for Children and Families.

**Steven M. Hanmer,**  
Reports Clearance, Officer.

[FR Doc. 2013-00592 Filed 1-15-13; 8:45 am]

BILLING CODE 4184-22-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0921]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

**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 February 15, 2013.

**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 emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0645. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**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.

#### Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803 (OMB Control Number 0910-0645)—Revision

The FDA Safety Reporting Portal (the SRP) (formerly referred to as the MedWatch<sup>Plus</sup> Portal and Rational Questionnaire) and the Electronic Submission Gateway (ESG) are the Agency's electronic systems for collecting, submitting, and processing adverse event reports and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, the Agency needs to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification

process is the first necessary step that allows the Agency to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a)). Many of the adverse event reports submitted to FDA are currently filed in paper format using FDA Forms FDA 3500, 3500A, 1932, and 1932a, approved under OMB control numbers 0910-0284 and 0910-0291. This notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, approved under OMB control number 0910-0645.

#### I. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive three types of adverse event reports electronically via the SRP using rational questionnaires. FDA sought comments on the extension of OMB approval for the existing three rational questionnaires, as well as comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the Center for Tobacco Products (CTP).

##### A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines "reportable food" as an "article of food (other than infant formula or dietary supplements) for which there is a reasonable

probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.” (See section 417(a)(2) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of FDA the responsibility for administering the FD&C Act, including section 417. To further the development of the RFR, section 417 of the FD&C Act required FDA to establish an electronic portal by which instances of reportable food (“RFR reports”) must be submitted to FDA by responsible parties and may be submitted by public health officials. A “responsible party” is the person who submits the registration under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. The RFR electronic portal was established in 2009 as part of the MedWatch<sup>Plus</sup> Portal, now the SRP, and approved under OMB control number 0910–0645.

The Congressionally identified purpose of the RFR is to provide “a reliable mechanism to track patterns of adulteration in food [which] would

support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health” (121 Stat. 965). The RFR reports are designed to enable FDA to quickly identify, track, and remove from commerce an article of food (other than infant formula and dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (Pub. L. 111–353) (the legislation or FSMA). Section 211 of the legislation amended section 417 of the FD&C Act to require FDA to collect additional information in the Agency’s RFR reports: (1) A description of the article of food; (2) affected product identification codes, such as universal product code (UPC), stock keeping unit, or lot or batch numbers sufficient for the consumer to identify the article of food; (3) contact information for the responsible party;

and (4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.

Section 211 of FSMA also amended section 417 of the FD&C Act to require FDA to generate one-page notices from RFR reports to post on *www.fda.gov* for grocery stores to display to consumers when a reportable food has been sold. The amendment made by section 211 of FSMA took effect June 4, 2012, 18 months after the date of enactment. To comply with this statutory deadline, FDA initially obtained OMB approval of the additional collection of information requirements under the emergency processing provisions of the PRA under OMB control number 0910–0709. The new data improves the RFR’s effectiveness in carrying out its purpose of tracking patterns of adulteration in food and supporting FDA’s efforts to target limited inspection resources to protect the public health.

Table 1 of this document, entitled “New Data Elements for RFR Reports,” presents the new data elements added by FDA to RFR Reports on June 4, 2012.

TABLE 1—NEW DATA ELEMENTS FOR RFR REPORTS

Field text	Mandatory or optional input	Authority if mandatory
Reason this food is reportable (agent) .....	Mandatory .....	Section 417(e)(4) of the FD&C Act.
What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?	Mandatory .....	Section 417(e)(5) of the FD&C Act.
How did you determine which products/lots/batches were affected?	Mandatory .....	Section 417(e)(4) and (5) of the FD&C Act.
To the best of your knowledge, has all of the reportable food been removed from commerce?	Mandatory .....	Section 417(e)(6) of the FD&C Act.
What corrective actions have been taken to prevent future occurrences?	Optional.	
Product commodity type .....	Mandatory .....	Section 417(e)(3) of the FD&C Act.
Manufacturing/production date(s) .....	Mandatory .....	Section 417(e)(3) and (4) of the FD&C Act.
Use-by dates, if any, or approximate shelf life .....	Mandatory .....	Section 417(e)(7) of the FD&C Act.
Was product treated to reduce microorganisms?	Mandatory (but conditional) .....	Section 417(e)(3) and (4) of the FD&C Act.
Microbial reduction treatment details .....	Mandatory (but conditional) .....	Section 417(e)(3) and (4) of the FD&C Act (Conditional for microbial hazards only and only after “yes” answer to “Was product treated to reduce microorganisms?”).
Is a bacterial isolate available for collection?	Mandatory (but conditional) .....	Section 417(e)(4) of the FD&C Act (Conditional for microbial hazards only.)
Animal species intended for .....	Mandatory .....	Section 417(e)(3) and (4) of the FD&C Act.
Life stage of animal intended for .....	Mandatory .....	Section 417(e)(3) and (4) of the FD&C Act.
Have you notified all immediate previous sources of this reportable food?	Optional.	
Have you notified all immediate subsequent recipients of this reportable food?	Mandatory .....	Section 417(e)(6) of the FD&C Act.

In this request for extension of OMB approval, FDA is combining the burden hours associated with OMB control number 0910–0709 with the burden

hours approved under this OMB control number (0910–0645).

*B. Reports Concerning Experience With Approved New Animal Drugs*

Section 512(l) of the FD&C Act (21 U.S.C. 360b(l)) and § 514.80(b)) require applicants of approved new animal drug

applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects.

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

If an applicant must report adverse drug experiences and product/manufacturing defects and chooses to do so using the Agency's paper forms, the applicant is required to use Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report." Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, "Transmittal of Periodic Reports and Promotional Material for New Animal Drugs" (see § 514.80(d)). Form FDA 1932a, "Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report" allows for voluntary reporting of adverse drug experiences or product/manufacturing defects. Collection of information using existing paper forms FDA 2301, 1932, and 1932a is approved under OMB control number 0910-0284. Alternatively, an applicant may choose to report adverse drug experiences and product/manufacturing defects electronically. Collection of this information electronically was approved in 2010 under OMB control number 0910-0645. The electronic submission data elements to report adverse drug experiences and product/manufacturing defects electronically remain unchanged in this request for extension of OMB approval.

#### C. Pet Food Early Warning System

Section 1002(b) of FDAAA directed the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. As part of the effort to fulfill that directive, the Secretary tasked FDA with developing the instrument that would allow consumers to report voluntarily adverse events associated with pet food.

FDA developed the Pet Food Early Warning System rational questionnaire

as a user-friendly data collection tool, to make it easy for the public to report a safety problem with pet food. The Pet Food Early Warning System is designed to identify adulteration of the pet food supply and outbreaks of illness associated with pet food to enable FDA to quickly identify, track and remove from commerce such articles of food. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. In 2010, OMB approved the Pet Food Early Warning System component of the SRP under OMB control number 0910-0645, and FDA launched the rational questionnaire by which consumers may electronically report adverse events associated with pet food. The electronic submission data elements to report adverse events associated with pet food remain unchanged in this request for extension of OMB approval.

#### D. Voluntary Tobacco Product Adverse Event and Product Problem Reports

As noted, this notice seeks comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the CTP to collect voluntary tobacco product adverse event and product problem reports.

FDA has broad legal authority under the FD&C Act to protect the public health. CTP's mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others. The Family Smoking Prevention and Tobacco Control Act of 2009 (Pub. L. 111-31) (Tobacco Control Act) amended the FD&C Act by creating a new section 909 (21 U.S.C. 387i, Records and Reports on Tobacco Products). Section 909(a) of the FD&C Act (21 U.S.C. 387i(a)) authorizes FDA to establish regulations with respect to mandatory adverse event reports associated with the use of a tobacco product. At this time, FDA is proposing to collect voluntary adverse event reports associated with the use of tobacco products from interested parties such as health care providers, researchers, consumers and other users of tobacco products. Information collected in voluntary adverse event reports will contribute to CTP's ability to be informed of, and assess the real consequences of, tobacco product use. The need for this collection of information derives from our objective

to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

CTP currently receives adverse event and product problem reports primarily via paper MedWatch forms, approved under OMB control number 0910-0291. MedWatch forms, although recently updated with field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products, do not specifically include questions relevant for the analysis of adverse events or product problems related to tobacco products. The proposed voluntary tobacco product adverse event and product problem rational questionnaire will include these specific questions. The questionnaire evolved with input from a National Institutes of Health team of human-factors experts, from other regulatory Agencies, and with extensive input from consumer advocacy groups and the general public. FDA is also working with the FDA Internet team to follow the Department of Health and Human Services Internet guidelines for Web design. FDA has and will continue to reach out to professional organizations and community interest groups to collect feedback during the user acceptance testing. The rational questionnaire will provide the user with detailed navigation instructions to include drop-down menus, lists of values, controlled vocabularies, and mouse over help where possible. In addition, CTP will issue guidance for the rational questionnaire. Finally, we note that users who are unable to submit reports using the electronic system will still be able to provide their information by paper form (by mail or FAX) or telephone.

The proposed voluntary tobacco product adverse event and product problem rational questionnaire requests the following information:

#### Introductory Information About the Submission

- Whether the submission is a new report, or a followup or amendment to a previously transmitted report.

#### Information About the Sender and the Affected Person

- Unless the sender wishes to remain anonymous, the name of and contact information for the person sending the report; and
- Unless the affected person wishes to remain anonymous, the name, contact

information, and demographic information for the person who experienced the adverse event.

Details of Any Attachments

- The type of attachment and a description of it.

Tobacco Product Details

- Information about the product that is the subject of the report, such as the brand name, product name, UPC, and a description of the tobacco product or component;
- Information about the product or component purchase date and location; and
- Information about the manufacturer of the product or component.

Problem Summary

- Information about the product problem or adverse event, such as the date and duration of the problem or adverse event, a description of the use of the product, a description of the product problem or adverse event, and a description of the main symptoms or health problems.

- Information about the medical treatment received by the affected person, such as whether the person was taken to an emergency facility, a description of any medical testing or treatment performed, and the results of any tests;
- Information about any similar product problems or adverse events previously had by the affected person; and
- In the event of death, the date of death and the reported cause of death.

Other Products Used

- Information about the affected person's use of other tobacco products, alcohol, prescription medications, over-the-counter medications, vitamins, or dietary supplements.
- The rational questionnaire will capture tobacco-specific adverse event and product problem information from voluntary reporting entities such as health care providers, researchers, consumers, and other users of tobacco products. To carry out its responsibilities, FDA needs to be informed when an adverse event,

product problem, or error with use is suspected or identified. When FDA receives tobacco-specific adverse event and product problem information, it will use the information to assess and evaluate the risk associated with the product, and then FDA will take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

In the **Federal Register** of September 14, 2012 (77 FR 56847), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

**II. Information Collection Burden Estimate**

*Description of respondents:* The respondents to this collection of information include all persons submitting mandatory or voluntary adverse event reports electronically to FDA via the ESG or the SRP.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary Adverse Event Report via the SRP (Other than RFR Reports). . . . .	3800	1,513	1	1,513	0.6 (36 minutes)	908
Mandatory Adverse Event Report via the SRP (Other than RFR Reports). . . . .	3800	636	1	636	1	636
Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission). . . . .	3800	1,491,228	1	1,491,228	0.6 (36 minutes)	894,737
Mandatory and Voluntary RFR Reports via the SRP. . . . .	3800	1,413	1	1,413	0.6 (36 minutes)	848
Total . . . . .						897,129

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The Agency's estimate of the number of respondents and the total annual responses in table 2, Estimated Annual Reporting Burden, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses are based on initial reports. Followup reports, if any, are not counted as new reports. Based on its experience with adverse event reporting, FDA estimates that it will take a respondent 0.6 hour to submit a voluntary adverse event report via the SRP, 1 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse

event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. FDA estimates that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary. Voluntary adverse event reports submitted via the SRP (other than RFR Reports) include reports associated with pet food (the Pet Food Early Warning System) and the new tobacco product adverse event and product problem reports. The Center for Veterinary Medicine (CVM) received 845 pet food adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012, and estimates

that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CVM estimates that it will receive, on average, 1,413 pet food reports annually over the next 3 years. CTP estimates that it will receive approximately 100 voluntary tobacco product adverse event and product problem reports annually, after implementation of electronic reporting. CTP received 27 reports in 2010, 30 reports in 2011, and 22 reports in the first half of 2012, and estimates that for the full 12 months of 2012 it will receive over 40 reports. Based on this experience and an expectation that reporting will increase once electronic

reporting is launched, CTP estimates that it will receive, on average, 100 voluntary adverse event and product problem reports annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 1,513 voluntary adverse event reports submitted via the SRP, with a burden of 907.8 hours, rounded to 908 hours, as reported in table 2, row 1 (1,413 + 100 = 1,513).

Mandatory adverse event reports submitted via the SRP (other than RFR Reports) include reports of adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. CVM received 144 such adverse event reports in 2010, 537 reports in 2011, and 212 reports in the first four months of 2012, and estimates that for the full 12 months of 2012 it will receive 636 reports. Based on this experience, CVM estimates that it will receive, on average, 636 reports of adverse drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 636 mandatory adverse event reports submitted via the SRP, with a burden of 636 hours, as reported in table 2, row 2.

Adverse event reports submitted via the ESG include reports of adverse experiences related to drugs, biological products, and medical devices, as well as, adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. FDA received 586,229 such adverse event reports in 2010; 850,161 reports in 2011; and 497,076 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,491,228 reports. Based on this experience, FDA estimates that it will receive, on average, 1,491,228 adverse event reports submitted via the ESG, with a burden of 894,736.8 hours, rounded to 894,737 hours, as reported in table 2, row 3.

FDA estimates that over the next 3 years it will receive annually 1,413 mandatory and voluntary RFR Reports submitted via the SRP, as reported in table 2, row 4. The Center for Food Safety and Applied Nutrition (CFSAN) received 845 such adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first four months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CFSAN estimates that it will receive, on average, 1,413 mandatory and voluntary RFR Reports submitted via the SRP annually over the next 3 years, with a burden of

847.8 hours, rounded to 848 hours, as reported in table 2, row 4.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910-0284 and 0910-0291.

While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from \$20 to \$30.

Dated: January 10, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-00761 Filed 1-15-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Optical Microscope Software for Breast Cancer Diagnosis

*Description of Technology:* The instant invention discloses a software to analyze optical microscopic images of human breast tissue sections for diagnosing cancer by using the differences in spatial positioning of

certain genes. The software uses the inherent hierarchy in the data and stores all the analysis and manual interaction information in a highly structured XML file. It is a user-friendly software to discriminate normal and cancerous human breast tissue section images that can be used for large experiments. Additionally the software uses a cluster of computers in the background to reduce the analysis time for large image datasets. Furthermore, the software of instant invention provides a set of tools for performing diagnostic or prognostic assays on new unseen datasets.

#### *Potential Commercial Applications:*

- The software could be an essential part of an integrated diagnostic or prognostic assay for breast cancer detection.

- The software could be a key tool for biomedical research to test new markers and their applicability for diagnostic purposes.

- The use of the software could provide important information for understanding the underlying causes of gene repositioning.

#### *Competitive Advantages:*

- The software of instant invention can be used to analyze relatively large datasets.

- To reduce the processing time by at least 10 fold.

- The software can be used in a broad range of quantitative image analysis applications.

#### *Development Stage:*

- Prototype
- Clinical
- In vitro data available (human)

*Inventors:* Kaustav Nandy (SAIC-Frederick, Inc), Stephen J. Lockett (SAIC-Frederick, Inc), Prabhakar R. Gudla (SAIC-Frederick, Inc), William Cukierski (NCI), Renee Qian (NCI), Karen J. Meaburn (NCI), Tom Misteli (NCI).

#### *Publications:*

1. Gudla PR, *et al.* A high-throughput system for segmenting nuclei using multiscale techniques. *Cytometry A*. 2008 May;73(5):451-66. [PMID 18338778]

2. Nandy K, *et al.* Automatic nuclei segmentation and spatial FISH analysis for cancer detection. *Conf Proc IEEE Eng Med Biol Soc*. 2009;2009:6718-21. [PMID 19963931].

3. Meaburn KJ, *et al.* Disease-specific gene repositioning in breast cancer. *J Cell Biol*. 2009 Dec 14;187(6):801-12. [PMID 19995938].

4. Cukierski WJ, *et al.* Ranked retrieval of segmented nuclei for objective assessment of cancer gene repositioning. *BMC Bioinformatics*. 2012 Sep 12;13:232. [PMID: 22971117].

5. Nandy K, *et al.* Supervised learning framework for screening nuclei in tissue