



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

January 17, 2019

23andMe, Inc.  
Lisa Charter  
Director, Regulatory Affairs and Quality Assurance  
899 West Evelyn Ave  
Mountain View, CA 94041

Re: DEN170046

Trade/Device Name: 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants)

Regulation Number: 21 CFR 21 CFR 866.6090

Regulation Name: Cancer Predisposition Risk Assessment System

Regulatory Class: Class II

Product Code: QAZ

Dated: September 1, 2017

Received: September 5, 2017

Dear Ms. Charter:

This letter corrects our letter dated March 6, 2018.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) with the following indications for use:

The 23andMe Personal Genome Service (PGS) uses qualitative genotyping to detect select clinically relevant variants in genomic DNA isolated from human saliva collected from individuals  $\geq 18$  years with the Oragene Dx model OGD500.001 for the purpose of reporting and interpreting genetic health risks, including the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants). The 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) is indicated for reporting of the 185delAG and 5382insC variants in the BRCA1 gene and the 6174delT variant in the BRCA2 gene. The report describes if a woman is at increased risk of developing breast and ovarian cancer, and if a man is at increased risk of developing breast cancer or may be at increased risk of developing prostate cancer. The three variants included in this report are most common in people of Ashkenazi Jewish descent and do not represent the majority of BRCA1/BRCA2 variants in the general population. The test report does not describe a person's overall risk of developing any type of cancer, and the absence of a variant tested does not rule out the presence of other variants that may be cancer-related. This test is not a substitute for visits to a healthcare provider for recommended screenings or appropriate follow-up and should not be used to determine any treatments.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants), and substantially equivalent devices of this generic type, into Class II under the generic name “Cancer Predisposition Risk Assessment System.”

FDA identifies this generic type of device as: **Cancer Predisposition Risk Assessment System.**

A Cancer Predisposition Risk Assessment System is a qualitative in vitro molecular diagnostic system used for determining predisposition for cancer where the result of the test may lead to prophylactic screening, confirmatory procedures, or treatments that may incur morbidity or mortality to the patient. The test could help to inform conversations with a healthcare professional. This assessment system is for over-the-counter use. This device does not determine the person’s overall risk of developing any types of cancer. This test is not a substitute for visits to a healthcare provider for recommended screenings or appropriate follow-up and should not be used to determine any treatments.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On September 5, 2017, FDA received your De Novo requesting classification of the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

**Table 1 – Identified Risks to Health and Identified Mitigations**

Identified Risks to Health	Identified Mitigations
Incorrect understanding of the device and test system	General controls and special controls (1), (3) and (4)
Incorrect test results (false positives, false negatives)	General controls and special controls (1), (2), (3) and (4)
Incorrect interpretation of test results	General controls and special controls (1), (3) and (4)

In combination with the general controls of the FD&C Act, a Cancer Predisposition Risk Assessment System is subject to the following special controls:

- (1) The 21 CFR 809.10 compliant labeling and any pre-purchase page and test report generated, unless otherwise specified, must include:
  - (i) An intended use that specifies in the indications for use the genetic variants detected by the test. The specific variants must be appropriately validated as described in paragraphs (b)(4)(xii) and (b)(4)(xiii) of this section.
  - (ii) A section addressed to users with the following information:
    - (A) A warning statement accurately disclosing the genetic coverage of the test in lay terms, including information on variants not queried by the test, and the proportion of pathogenic variants in the genes that the assay detects in a specific population as identified in paragraph (b)(1)(i) of this section. The warning statement must indicate that the test [does not/ may not, as appropriate] detect all genetic variants related to the genetic disease, and that the absence of a variant tested does not rule out the presence of other genetic variants that may impact cancer risk. The warning statement must also include the relevant population for which the variants reported by the test are most relevant.
    - (B) The limiting statement explaining that some people may feel anxious about getting genetic test health results. This is normal. If the potential user feels very anxious, such user should speak to his or her doctor or other healthcare professional prior to collection of a sample for testing. This test is not a substitute for visits to a doctor or other healthcare professional. Users should consult with their doctor or other healthcare professional if they have any questions or concerns about the results of their test or their current state of health.
    - (C) The limiting statement that a user’s ethnicity may affect whether the test is relevant for them and may also affect how their genetic health results are interpreted.
    - (D) A warning statement that the test is not a substitute for visits to a healthcare professional for recommended screenings, and should not be used to determine any treatments or medical interventions.

- (E) A warning statement that the test does not diagnose cancer or any other health conditions and should not be used to make medical decisions. The warning statement must indicate that the results should be confirmed in a clinical setting before taking any medical action.
  - (F) The limiting statement explaining that other companies offering a genetic risk test may be detecting different genetic variants for the same disease, so the user may get different results using a test from a different company.
  - (G) If applicable, a limiting statement that states the test does not test for variants in other genes linked to hereditary cancer.
  - (H) The limiting statement explaining that this test does not account for non-genetic factors and that other factors such as environmental and lifestyle risk factors may affect the risk of developing a given disease.
  - (I) Information to potential purchaser or actual test report recipient about how to obtain access to a board-certified clinical molecular geneticist or equivalent to assist in pre- and post-test counseling.
  - (J) The limiting statement explaining that this test is not intended to tell you anything about your current state of health, or be used to make medical decisions, including whether or not you should take a medication or how much of a medication you should take.
  - (K) The limiting statement explaining that the laboratory may not be able to process a sample, and a description of the next steps to be taken by the manufacturer and/or the customer, as applicable.
- (iii) A section in your 21 CFR 809.10 labeling and any test report generated that is for healthcare professionals who may receive the test results from their patients with the following information:
- (A) The limiting statement explaining that this test is not intended to diagnose a disease, determine medical treatment or other medical intervention, or tell the user anything about their current state of health.
  - (B) The limiting statement explaining that this test is intended to provide users with their genetic information to inform health-related lifestyle decisions and conversations with their doctor or other healthcare professional.
  - (C) The limiting statement explaining that any diagnostic or treatment decisions should be based on confirmatory prescription testing and/or other information that is determined to be appropriate for the patient (e.g., additional clinical testing and other risk factors that may affect individual risk and health care).
- (2) The genetic test must use a sample collection device that is FDA-cleared, -approved, or -classified as 510(k) exempt, with an indication for *in vitro* diagnostic use in over-the-counter DNA testing.

(3) The device’s labeling must include a hyperlink to the manufacturer’s public website where the manufacturer shall make the information identified in paragraph (b)(3) of this section publicly available. The manufacturer’s home page, as well as the primary part of the manufacturer’s website that discusses the device, must provide a hyperlink to the Web page containing this information and must allow unrestricted viewing access. If the device can be purchased from the Web site or testing using the device can be ordered from the Web site, the same information must be found on the Web page for ordering the device or provided in a publicly accessible hyperlink on the Web page for ordering the device. Any changes to the device that could significantly affect safety or effectiveness would require new data or information in support of such changes, which would also have to be posted on the manufacturer’s website. The information must include:

- (i) An index of the material being provided to meet the requirements in paragraph (b)(3) of this section and its location.
- (ii) Technical information about the device, as specified in paragraph (b)(4) of this section.
- (iii) A section that highlights summary information that allows the user to understand how the test works and how to interpret the results of the test. This section must, at a minimum, be written in plain language understandable to a lay user and include:
  - (A) Consistent explanations of the risk of disease associated with all variants included in the test, variants not included in the test, and specific considerations by ethnicity. If there are different categories of risk, the manufacturer must provide literature references and/or data that support the different risk categories. If there will be multiple test reports and multiple variants, the risk categories must be defined similarly among them. For example, “increased risk” must be defined similarly between different test reports and different variant combinations.
  - (B) Clear context for the user to understand the context in which the cited clinical performance data support the risk reported. This includes, but is not limited to, any risks that are influenced by ethnicity, age, gender, environment, and lifestyle choices.
  - (C) Materials that explain the main concepts and terminology used in the test that include:
    - (1) Definitions: scientific terms that are used in the test reports.
    - (2) Pre-purchase page: this page must contain information that informs the user about what information the test will provide. This includes, but is not limited to, variant information, the condition(s) or disease(s) associated with the variant(s), professional guideline recommendations for general genetic risk testing, the limitations associated with the test (e.g., test does not detect all variants related to the disease), relevance of race/ethnicity, and any precautionary information about the test the user should be aware of before purchase. When the test reports the risk of a life-threatening or irreversibly debilitating disease or condition for which there are few or no options to prevent, treat, or cure the disease, a user opt-in page must be provided. This

opt-in page must be provided for each disease type that falls into this category and must provide specific information relevant to each test result. The opt-in page must include:

- (i) An option to accept or decline to receive this specific test result;
- (ii) Specification of the risk involved if the user is found to have the specific genetic test result;
- (iii) Summary of professional guidelines that recommend when genetic testing for the associated target condition is or is not recommended;
- (iv) A recommendation to speak with a healthcare professional, genetic counselor, or equivalent professional before getting the results of the test;
- (v) The implications of receiving a no variants detected result; and
- (vi) The statement that the test does not diagnose cancer or any other health conditions and should not be used to make medical decision. Results should be confirmed in a clinical setting before taking any medical action. Users should consult with a healthcare professional before taking any medical action.

(3) Frequently asked questions (FAQ) page: This page must provide information that is specific for each variant/disease pair that is reported. Information provided in this section must be scientifically valid and supported by corresponding peer-reviewed publications. The FAQ page must explain the health condition/disease being tested, the purpose of the test, the information the test will and will not provide, the relevance of race and ethnicity to the test results, information about the population to which the variants in the test is most applicable, the meaning of the result(s), other risk factors that contribute to disease, appropriate follow-up procedures, how the results of the test may affect the user's family, including children, and links to resources that provide additional information.

(4) The device labeling must include a technical information section containing the following information:

- (i) Gene(s) and variant(s) the test detects using standardized nomenclature, Human Genome Organization (HUGO) nomenclature and coordinates as well as Single Nucleotide Polymorphism Database (dbSNP) reference SNP numbers (rs#).
- (ii) A statement indicating that more than 1,000 variants in the BRCA1 and BRCA2 genes are known to increase cancer risk, as applicable.

(iii) Scientifically established disease-risk association of each variant detected and reported by the test. This risk association information must include:

- (A) Genotype-phenotype information for the reported variants.
  - (B) When available, a table of expected frequency in the general population and different ethnicities, and risks of developing the disease in relevant ethnic populations and the general population.
  - (C) Information such as peer reviewed published literature and/or professional guidelines used to determine what types and levels of evidence will distinguish whether the selected variants are reported as “are associated with increased risk” versus “may be associated with increased risk” of developing other cancers. All selected variants must be appropriately validated as required under paragraph (b)(1)(i) of this section. For selected variants reported as “are associated with increased risk”, the clinical evidence must be demonstrated with sufficient information (e.g., professional guidelines and consistent associations in peer-reviewed published literature). For the selected variants reported as “may be associated with increased risk”, the clinical evidence must be reported in professional guidelines but peer-reviewed published literature may not be consistent.
  - (D) A statement about the current professional guidelines for testing these specific gene(s) and variant(s) for the specified disease(s).
    - (1) If professional guidelines are available, provide the recommendations in the professional guideline(s) for the gene, variant, and disease, for when genetic testing should or should not be performed, and cautionary information that should be communicated when a particular gene and variant is detected.
    - (2) If professional guidelines are not available, provide a statement that the professional guidelines are not available for these specific gene(s) and variant(s).
- (iv) The specimen type (e.g., saliva, whole blood).
- (v) Assay steps and technology used.
- (vi) Specification of required ancillary reagents, instrumentation, and equipment.
- (vii) Specification of the specimen collection, processing, storage, and preparation methods.
- (viii) Specification of risk mitigation elements and description of all additional procedures, methods, and practices incorporated into the directions for use that mitigate risks associated with testing.

- (ix) Information pertaining to the probability of test failure (e.g., percentage of tests that failed quality control) based on data from clinical samples, a description of scenarios in which a test can fail (i.e., low sample volume, low DNA concentration, etc.), how users will be notified of a test failure, and the nature of follow-up actions on a failed test to be taken by the user and the manufacturer.
- (x) When available, information specifying the probability of a false negative and false positive analytical result and any additional considerations by ethnicity.
- (xi) Specification of the criteria for test result interpretation and reporting, including any distinctions between risk categories (i.e., increased risk and greatly increased risk; are associated and may be associated).
- (xii) Information that demonstrates the performance characteristics of the test including:
  - (A) Accuracy of study results for each claimed specimen type.
    - (1) Accuracy of the test shall be evaluated with fresh clinical specimens collected and processed in a manner consistent with the test's instructions for use. If this is impractical, fresh clinical samples may be substituted or supplemented with archived clinical samples. Archived samples shall have been collected previously in accordance with the instructions for use, stored appropriately, and randomly selected. In some limited circumstances, use of contrived samples or human cell line samples may also be appropriate and used as an acceptable alternative. The contrived or human cell line samples shall mimic clinical specimens as much as is feasible and provide an unbiased evaluation of the test's accuracy.
    - (2) Accuracy must be evaluated by comparison to bidirectional Sanger sequencing or other methods identified as appropriate by FDA. Performance criteria for both the comparator method and the test must be pre-defined and appropriate to the test's intended use. Detailed study protocols must be provided.
    - (3) Information provided shall include the number and type of specimens, broken down by clinically relevant variants for each indicated report that were compared to bidirectional sequencing or other methods identified as appropriate by FDA. The accuracy as positive percent agreement (PPA) and negative percent agreement (NPA), must be measured, and accuracy point estimates must be >99% (both per reported variant and overall). Uncertainty of the point estimate must be within an acceptable range, as identified by FDA, and must be presented using the 95% confidence interval.



- (4) Sufficient specimens must be tested per genotype and must include all genotypes that will be included in the tests and reports. The number of samples tested in the accuracy study for each variant reported must be based on the variant frequency.
  - (5) Any no calls (i.e., absence of a result) or invalid calls (e.g., failed quality control) in the study must be included in accuracy study results and reported separately. The percent of final ‘no calls’ or ‘invalid calls’ must be clinically acceptable. Variants that have a point estimate for PPA or NPA of <99% (incorrect test results compared to bidirectional sequencing or other methods identified as appropriate by FDA) must not be incorporated into test claims and reports. Accuracy measures generated from clinical specimens versus contrived samples or cell lines must be presented separately. Results must be summarized and presented in tabular format, by sample and by genotype.
  - (6) Point estimate of PPA for each genotype must be calculated as the number of correct calls for that genotype divided by the number of samples known to contain that genotype. The point estimate of NPA for each genotype should be calculated as the number of correct calls that do not contain that genotype divided by the number of samples known to not contain that genotype. ‘No calls’ should not be included in these calculations. Point estimates should be calculated along with 95% two-sided confidence intervals.
- (B) Precision and reproducibility data must be provided using multiple instruments and multiple operators, on multiple non-consecutive days, and using multiple reagent lots. The sample panel must include specimens from the claimed sample type (e.g., saliva) representing all genotypes for each variant (e.g., wild type, heterozygous, and homozygous). Performance criteria must be predefined. A detailed study protocol must be created in advance of the study and then followed. The failed quality control (FQC) rate must be indicated (i.e., the total number of sample replicates for which a sequence variant cannot be called (no calls) or that fail sequencing quality control (QC) criteria divided by the total number of replicates tested). It must be clearly documented whether results were generated from clinical specimens, contrived samples, or cell lines. The study results shall state, in a tabular format, the variants tested in the study and the number of replicates for each variant, and what conditions were tested (i.e., number of runs, days, instruments, reagent lots, operators, specimens/type, etc.). The study must include all extraction steps from the claimed specimen type or matrix, unless a separate extraction study for the claimed sample type is performed. If the device is to be used at more than one laboratory, different laboratories must be included in the precision study (and reproducibility across sites must be evaluated). Any no calls or invalid calls in the study must be listed as a part of the precision and reproducibility study results.

- (C) Analytical specificity data: data must be provided evaluating the test performance (e.g., specimen extraction and variant detection) effect of potential endogenous and exogenous interferents relevant to the specimen type, and assessment of cross-contamination. Alternatively, for each suspected interfering mutation for which data is not provided demonstrating the effect of the interfering variant, the manufacturer must clearly identify the suspected interfering variants in the labeling, including but not limited to user test reports, and indicate that the impact the interfering variants may have on the test's performance has not been studied by providing a statement that reads, "It is possible that the presence of [insert identifying information for the suspected interfering variant] in a sample may interfere with the performance of this test. However, its effect on the performance of this test has not been studied."
- (D) Analytical sensitivity data: data must be provided demonstrating the minimum amount of DNA that will enable the test to perform correctly in 95% of runs.
- (E) Device stability data: the manufacturer must establish upper and lower limits of input nucleic acid, sample, and reagent stability that will achieve the test's claimed accuracy and reproducibility. The manufacturer must evaluate stability using wild-type, heterozygous, and homozygous samples. Data supporting such claims must be provided.
- (F) Specimen Type and matrix comparison data: specimen type and matrix comparison data must be generated if more than one specimen type can be tested with this device, including failure rates for the different specimens.

(xiii) Clinical Performance Summary

- (A) Information to support the clinical performance of each variant in the specific condition which is labeled as "are associated with increased risk" and reported by the test must be provided, as identified in paragraph (b)(4)(iii)(C) of this section.
- (B) Manufacturers must organize information by the specific variant combination as appropriate (e.g., wild type, heterozygous, homozygous, compound heterozygous, hemizygous genotypes). For each variant combination, information must be provided in the clinical performance section to support clinical performance for the risk category (e.g., not at risk, increased risk). For each variant combination, a summary of key results must be provided in tabular format or using another method identified as appropriate by FDA to include the appropriate information regarding variant type, data source, definition of the target condition (e.g., disease), clinical criteria for determining whether the target disease is present or absent, description of subjects with the target disease present and target disease absent (exclusion or inclusion criteria), and technical method for genotyping. When available, information on the

effect of the variant on risk must be provided as the risk of a disease (lifetime risk or lifetime incidences) for an individual compared with the general population risk.

- (xiv) User comprehension study: information on a study that assesses comprehension of the test process and results by potential users of the test, must be provided, including the following, as appropriate:
- (A) The test manufacturer must provide a genetic health risk education module to naïve user comprehension study participants prior to their participation in the user comprehension study. The module must define terms that are used in the test reports and explain the significance of genetic risk reports.
  - (B) The test manufacturer must perform pre- and post-test user comprehension studies. The comprehension test questions must directly evaluate the material being presented to the user as described in paragraph (b)(3)(ii).
  - (C) The manufacturer must provide a justification from a physician and/or genetic counselor that identifies the appropriate general and variant-specific concepts contained within the material being tested in the user comprehension study to ensure that all relevant concepts are incorporated in the study.
  - (D) The user study must meet the following criteria:
    - (1) The study participants must comprise a statistically sufficient sample size and demographically diverse population (determined using methods such as quota-based sampling) that is representative of the intended user population. Furthermore, the study participants must comprise a diverse range of age and educational levels and have no prior experience with the test or its manufacturer. These factors shall be well-defined in the inclusion and exclusion criteria.
    - (2) All sources of bias (e.g., non-responders) must be predefined and accounted for in the study results with regard to both responders and non-responders.
    - (3) The testing must follow a format where users have limited time to complete the studies (such as an on-site survey format and a one-time visit with a cap on the maximum amount of time that a participant has to complete the tests).
    - (4) Users must be randomly assigned to study arms. Test reports in the user comprehension study given to users must define the target condition being tested and related symptoms, explain the intended use and limitations, including warnings, for the test, explain the relevant ethnicities in regard to the variant tested, explain genetic

health risks and relevance to the user's ethnicity, and assess participants' ability to understand the following comprehension concepts: the test's limitations, purpose, appropriate action, test results and other factors that may have an impact on the test results.

- (5) Study participants must be untrained, be naïve to the test subject of the study, and be provided the labeling prior to the start of the user comprehension study.
- (6) The user comprehension study must meet the predefined primary endpoint criteria, including a minimum of a 90 percent or greater overall comprehension rate (i.e., selection of the correct answer) for each comprehension concept. Other acceptance criteria may be acceptable depending on the concept being tested. Meeting or exceeding this overall comprehension rate demonstrates that the materials presented to the user are adequate for over-the-counter use.
- (7) The analysis of the user comprehension results must include:
  - (i) Results regarding reports that are provided for each gene/variant/ethnicity tested;
  - (ii) Statistical methods used to analyze all data sets; and
  - (iii) Completion rate, non-responder rate, and reasons for nonresponse/data exclusion. A summary table of comprehension rates regarding comprehension concepts (e.g., purpose of test, test results, test limitations, ethnicity relevance for the test results, appropriate actions following receipt of results, etc.) for each study report must be included.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Cancer Predisposition Risk Assessment System they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Soma Ghosh, Ph.D. at 240-402-5333.

Sincerely,

Reena Philip, Ph.D.  
Director  
Division of Molecular Genetics and Pathology  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health