

April 22, 2005

Transmitted Via
EDGAR and Facsimile

Ms. Kate Tillan
Assistant Chief Accountant
Securities and Exchange Commission
Division of Corporation Finance
450 Fifth Street, N.W.
Washington, D.C. 20549

Re: OraSure Technologies, Inc. Form 10-K for the
Year Ended December 31, 2004 ("10-K Report")
SEC File No. 1-16537

Dear Ms. Tillan:

In response to your letter dated April 8, 2005 (the "Comment Letter") with respect to the above-referenced 10-K Report, OraSure Technologies, Inc. ("OraSure" or the "Company") is providing the following responses and supplemental information in response to the Staff's comments. The responses set forth below are labeled to correspond to the numbers assigned by the Staff to its comments.

Comment 1

In response to this Comment, the Company's future filings will be revised to indicate the conclusions reached by the Company's Chief Executive Officer and Chief Financial Officer in evaluating whether the Company's disclosure controls and procedures are effective in ensuring that information required to be disclosed by the Company in its reports is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "Commission"). This disclosure will thus incorporate the definition of "disclosure controls and procedures" set forth in Exchange Act Rule 13a-15(e).

Comment 2

Item 308(c) of Regulation S-K requires the disclosure of any change in the Company's internal control over financial reporting "identified in connection" with the evaluation required by Exchange Act Rule 13a-15(c) or 15d-15(c) that occurred during the Company's last fiscal quarter (or fourth quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company's future filings will be revised to indicate whether there was any change "identified in connection" with each such evaluation performed by the Company.

Comment 3

The following are responses to Comments regarding the Company's revenue recognition policies:

(A) Supplementally, we advise the Staff that the Company maintains contractual agreements pursuant to which certain distributors are entitled to receive annual volume rebates. Rebates are based upon each distributor's targeted sales of our products. Historically, these distributors have met or exceeded the targets included in their respective agreements. As such, in accordance with Emerging Issues Task Force ("EITF") Issue No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Product), we account for these rebates in our financial statements as a direct reduction of the underlying monthly revenues derived from these distributors. Rebates are accrued monthly and paid to these distributors, in arrears. For the years ended December 31, 2004, 2003 and 2002, we reduced our product revenues by approximately [*A01], respectively, for these rebates. These rebates represent [*A02] of total product revenues for the years ended December 31, 2004, 2003 and 2002, respectively. As requested by this Comment, the Company will provide, in future filings, further disclosure on the nature, terms and related accounting treatment of rebates recognized in each period presented, to the extent they are material.

(B) Supplementally, we would like to advise the Staff of the nature of the Company's "reagent rental" agreements, which we have executed with a limited number of customers. As disclosed in the Company's filings, we develop and sell a variety of immunoassay tests and reagents, in formats tailored to meet the specific needs of our customers. Our immunoassay tests and reagents are sold to national testing firms, as well as smaller local laboratories. These laboratory tests are performed exclusively on automated analytical instruments. The term "reagent rental" is specific to our industry and is used to describe a contract under which a new customer purchases tests or reagents from us at an agreed-upon price, usually over a multi-year period. These customers, however, desire to perform testing via an automated analytical instrument, but they do not have one in-house. Pursuant to a "reagent rental" agreement, in exchange for an increased price per test and a commitment by the customer to purchase a minimum number of tests, the Company supplies the customer with a small piece of analytical equipment for use in processing. In essence, the customer pays a higher price for immunoassay tests or reagents than it would if it had its own equipment. The Company monitors the purchases made by customers who have executed these agreements. Generally, these customers meet their minimum purchase requirements. Because utilization of an instrument by our customer is dependent upon the specific immunoassay tests and reagents purchased by them, and these same immunoassay tests cannot be performed without the instrument, the Company recognizes revenue when we ship non-returnable immunoassay tests and reagents to these customers. The Company does not recognize any separate revenue related solely to the analytical instrument provided to and used by our customer.

Prior to entering into a reagent rental agreement with a customer, the Company purchases the equipment from a third-party vendor. The average cost of this equipment is approximately \$[*A03]. The Company retains title to the equipment and the customer is required to return it to

us at the end of the contract period. The cost of the equipment is capitalized in the Company's financial statements and amortized on a straight-line basis over five years, with the resulting depreciation expense recorded in cost of goods sold in our statement of operations. Related maintenance costs are expensed as incurred. As supplemental information, revenues related to the sale of immunoassay tests or reagents under these agreements were approximately \$[*A04], or [*A05]% of product revenues for the years ended December 31, 2004, 2003 and 2002, respectively. It is anticipated that revenues from these agreements will continue to decline in the future, as the Company does not actively pursue this type of business. Gross margin recognized from these revenues was approximately \$[*A06] or [*A07]% of total gross margin realized in the years ended December 31, 2004, 2003 and 2002, respectively. As requested by this Comment, we will disclose, in future filings, the nature, significant terms and related accounting treatment for these agreements, if material.

(C) Supplementally, we would like to advise the Staff of the nature, timing and measurement of revenues related to the sale of our OraSure® HIV-1 testing kits, as well as the terms of the contractual agreements that we have with two national laboratories. As indicated in our 10-K Report, the Company sells a prepackaged OraSure® HIV-1 testing kit, comprised of an oral fluid collection device coupled with prepaid laboratory testing and shipping services. These kits are marketed to various community-based clinics, agencies, and state and local public-health organizations. These organizations generally do not have a third-party laboratory relationship or the ability to perform laboratory testing in-house. The Company, however, has negotiated laboratory testing service agreements with two national laboratories, LabOne, Inc. and Heritage Labs International, LLC, pursuant to which these laboratories have agreed to provide HIV-1 testing services on oral fluid samples submitted by our kit customers. Accordingly, our kit customers collect an oral fluid sample from their clients, and then forward the sample to one of these prescribed laboratories for testing and confirmation. The laboratory invoices the Company for the testing services, at the contracted price, once the services have been rendered.

The Company concurs with the Staff in the treatment of these kit sales as revenue arrangements with multiple-deliverables. The Company accounts for revenues derived from OraSure® testing kits in accordance with the authoritative guidance included in Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements, and EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. Revenues derived from OraSure® testing kits are divided into two separate units of accounting, the non-returnable OraSure® oral-fluid collection device and the laboratory testing services. The OraSure® collection device has stand-alone value to our customer, as it can be used readily with any laboratory and it can be sold commercially on a stand-alone basis. Likewise, HIV testing services are commercially available from a wide variety of laboratories. As such, we believe there is objective, reliable and verifiable evidence of the fair value for the collection device and testing service. In addition, there are no rights of return associated with our testing kits, other than for warranty issues. Accordingly, revenues are allocated based upon the relative fair values of the device and testing services. Revenue associated with the non-returnable oral fluid collection device is recognized upon shipment of the kit to our customer. Revenue associated with the testing service, however, is deferred, since the testing service has not yet been rendered. Generally, we recognize this deferred revenue over a four-to-six month period, when the designated laboratories render the testing service. Recognition is based upon information provided to us by the laboratories and receipt of their invoices for the related testing services.

The Company's revenue recognition policy as it relates to these testing kits has been consistently applied in all periods presented in our 10-K Report. As supplemental information, net revenues derived from sales of OraSure® HIV-1 testing kits were approximately \$[*A08] or [*A09]% of product revenues for the years ended December 31, 2004, 2003 and 2002, respectively. Gross margin recognized from these revenues was approximately \$[*A10] or [*A11]% of total gross margin realized in the years ended December 31, 2004, 2003 and 2002, respectively. In October 2004, the Company commercially launched a new product, the OraQuick® *ADVANCE* HIV-1/2 test. As previously disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations for the twelve months ended December 31, 2004 compared to December 31, 2003, in our 10-K Report, sales of the OraSure® HIV-1 testing kits are expected to decline, as customers switch to the new OraQuick® *ADVANCE* HIV-1/2 test. As requested by this Comment, we will disclose, in future filings, the nature, significant terms, and related accounting treatment for these agreements, if material.

(D) Supplementally, we would like to advise the Staff of the terms and conditions related to our sales of laboratory testing equipment, often referred to in our industry as automated analytical instruments, as well as the manner in which the Company accounts for these revenues. As noted in this Comment, the Company purchases equipment from third-party vendors, for resale to a limited number of our customers. Based upon the customer's specifications, we also license, from an outside vendor, an operating software program required to facilitate the customer's testing protocol on the related analytical instrument. Our technicians install the software into the instrument and then test the instrument's functionality to ensure that it will operate in the same manner in the customer's environment as it does in our facility. We then sell the complete unit to our customer as a turnkey solution to their testing needs.

The Company accounts for revenue derived from equipment sales in accordance with EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent. We record equipment revenues on a gross basis, given we act as a principal in the transaction with our customer, we take title to the equipment upon our purchase of it, we install software and test the equipment's functionality, and we bear the risks of ownership associated with the equipment until it is sold to the customer. When we initially purchase the equipment and software for resale, we capitalize it as inventory. When we ship the completed instrument to our customer, we simultaneously recognize this equipment sale as product revenues, and the related costs of the equipment and software, as cost of goods sold, in our statement of operations. The average selling price of a completed unit is approximately \$[*A12]. Our contract with our customer does not contain any customer specific acceptance provisions, we do not offer any type of extended warranties or rights of return and we do not have any ongoing obligation to install or service the equipment. Should a customer wish to lease a piece of equipment, we offer to introduce them to leasing organizations familiar with this type of equipment, however, the customer must secure its own financing independent of the Company. The Company does not lease equipment to customers. We deem equipment sales to be an insignificant part of our business and as such, we do not actively pursue additional business in this segment of the diagnostics market. As supplemental information, revenues recognized from equipment sales

were approximately \$[*A13] or [*A14]% of product revenues for the years ended December 31, 2004, 2003 and 2002, respectively. Gross margin recognized from these revenues was approximately \$[*A15] or [*A16]% of total gross margin realized in the years ended December 31, 2004, 2003 and 2002, respectively. As requested by this Comment, we will disclose, in future filings, the nature, significant terms, and related accounting treatment for these agreements, if material.

In connection with the foregoing responses, the Company acknowledges that (i) the Company is responsible for the adequacy and accuracy of the disclosure in its filings; (ii) Staff comments or changes to disclosure in response to Staff comments in the filings reviewed by the Staff do not foreclose the Commission from taking any action with respect to the filing; and (iii) the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please do not hesitate to contact the undersigned (610-882-1820, ext. 3279) if you have any questions or if we can provide any further information that would be helpful to the Staff.

Sincerely,

/s/ Ronald H. Spair

Ronald H. Spair
Executive Vice President
and Chief Financial Officer

cc: D. Michels, President and Chief Executive Officer
J. Jerrett, Senior Vice President and General Counsel
M. Kuna, Vice President and Controller
E. Stortz, Financial Reporting Specialist
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J. Gerard, KPMG LLP
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