

*Changes in estimates:* There is no change of hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This universe of respondents remains the same. The changes in costs are due to inflation and an increase in wages for respondents, rounded to 3 significant figures.

**Courtney Kerwin,**

*Director, Regulatory Support Division.*

[FR Doc. 2018-04055 Filed 2-27-18; 8:45 am]

**BILLING CODE 6560-50-P**

## FEDERAL MARITIME COMMISSION

### Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's website ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202) 523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 012442-001.

*Title:* Miami Marine Terminal Conference Agreement.

*Parties:* Port of Miami Terminal Operating Company, L.C. and South Florida Container Terminal, LLC.

*Filing Party:* David F. Smith; Cozen O'Connor; 1200 19th Street NW, Washington, DC 20036.

*Synopsis:* The amendment revises Article 3 of the Agreement to correct the name of one of the Agreement Parties, the Port of Miami Terminal Operating Company, L.C.

By Order of the Federal Maritime Commission.

Dated: February 23, 2018.

**Rachel E. Dickon,**

*Secretary.*

[FR Doc. 2018-04080 Filed 2-27-18; 8:45 am]

**BILLING CODE 6731-AA-P**

## FEDERAL TRADE COMMISSION

[File No. 142 3103]

### Telomerase Activation Sciences, Inc. and Noel Thomas Patton; Analysis To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of

federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before March 23, 2018.

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: “In the Matter of Telomerase Activation Sciences, Inc., et al.” on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/telomeraseconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “In the Matter of Telomerase Activation Sciences, Inc., et al.” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:**

Andrew Wone (202-326-2934), Bureau of Consumer Protection, 600 Pennsylvania Avenue NW, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for February 21, 2018), on the World Wide Web, at <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 23, 2018. Write “In the Matter of Telomerase Activation

Sciences, Inc., et al.” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at <https://www.ftc.gov/policy/public-comments>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/telomeraseconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov#!home>, you also may file a comment through that website.

If you prefer to file your comment on paper, write “In the Matter of Telomerase Activation Sciences, Inc., et al.” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at <https://www.ftc.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs,

sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 23, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

#### **Analysis of Proposed Consent Order To Aid Public Comment**

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order as to Telomerase Activation Sciences, Inc. and Noel Thomas Patton (collectively "respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's order.

This matter involves respondents' advertising for TA-65MD, a product that comes in capsule and powder forms, and TA-65 for Skin ("TA-65 Skin"), a topical cream product. The

complaint alleges that respondents violated Sections 5(a) and 12 of the FTC Act by making false or unsubstantiated health or performance claims that: TA-65MD and TA-65 Skin reverse aging; TA-65MD prevents and repairs DNA damage; TA-65MD restores aging immune systems; TA-65MD increases bone density; TA-65MD reverses the effects of aging, including improving skin elasticity, increasing energy and endurance, and improving vision; TA-65MD prevents or reduces the risk of cancer; TA-65 Skin reverses the effects of aging, including improving skin elasticity; and TA-65 Skin decreases recovery time of the skin after medical procedures. The complaint also alleges that respondents claimed that some of the above performance claims were clinically or scientifically proven.

The complaint further alleges that respondents misrepresented that a 2012 paid-for segment on *The Suzanne Show* featuring TA-65MD was independent, educational programming and not paid commercial advertising. Additionally, the complaint alleges that respondents deceptively represented that consumers appearing in advertisements were independent users of TA-65MD, expressing their impartial views of satisfaction. According to the complaint, respondents failed to disclose that these consumer endorsers received compensation, including free TA-65MD. Finally, the complaint alleges that by providing promotional materials that had false or unsubstantiated health or performance claims to marketers of other products containing TA-65MD, respondents provided these other marketers the means and instrumentalities to engage in deceptive acts and practices.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The order applies to marketing claims for any covered product, defined as TA-65MD and TA-65 Skin or any other drug, food, dietary supplement, or cosmetic. As additional fencing-in relief, the order requires respondents to provide a notice to all of its licensees authorized to advertise, market, or sell any covered product, monitor certain high-selling licensees, and follow appropriate recordkeeping, compliance reporting, and document preservation requirements.

*Provision I* prohibits any representation that a covered product reverses human aging; prevents or repairs DNA damage; restores aging immune systems; increases bone density; reverses the effects of aging, including improving skin elasticity, increasing energy and endurance, and

improving vision; decreases recovery time of the skin after medical procedures; prevents or reduces the risk of cancer; or cures, mitigates, or treats any disease unless the representation is non-misleading and respondents possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. The definition of competent and reliable scientific evidence in Provision I specifies human clinical testing and requires that the testing be sufficient in quality and quantity, based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must (1) be randomized, double-blind, and placebo-controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, respondents must maintain all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing.

*Provision II* prohibits representations regarding the health benefits, performance, efficacy, safety, or side effects of any covered product unless the representation is non-misleading and respondents possess and rely upon competent and reliable scientific evidence to substantiate that the representation is true. Provision II defines competent and reliable scientific evidence as tests, analyses, research, or studies: (1) That have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, when such experts would generally require such human clinical testing to substantiate that the representation is true. When such tests or studies are human clinical tests or studies, respondents must maintain all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing.

*Provision III* prohibits misrepresentations that any covered product is clinically or scientifically proven to reverse human aging, prevent or repair DNA damage, restore aging immune systems, or increase bone density. Provision III also prohibits any misrepresentation that the performance

or benefits of any product are scientifically or clinically proven or about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

*Provision IV* is a provision for FDA-approved claims.

*Provision V* prohibits misrepresentations in connection with the marketing, advertising, or promoting of any product, service, or program that paid commercial advertising is independent programming.

*Provision VI* prohibits any representation about any user, consumer, or endorser of a covered product without disclosing, clearly and conspicuously, and in close proximity to that representation, any unexpected material connection between such endorser and (1) any respondent; or (2) any other individual or entity affiliated with the product. "Unexpected material connection" means any relationship that might materially affect the weight or credibility of the testimonial or endorsement and that would not reasonably be expected by consumers.

*Provision VII* prohibits misrepresentations regarding the status of any endorser or person providing a review of a product, including a misrepresentation that the endorser or reviewer is an independent or ordinary user of the product.

*Provision VIII* prohibits respondents from providing the means and instrumentalities to make any false or misleading statement of material fact, including the representations prohibited by Provisions I to III. "Means and instrumentalities" mean any information, document, or article referring or relating to any covered product, including any advertising, labeling, promotional, or purported substantiation materials, for use by a licensee to market or sell any covered product.

*Provision IX*, triggered when the human clinical testing requirement in Provisions I or II applies, requires that respondents secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a reliably reported test (defined as a test that is published in a peer-reviewed journal) that was not conducted, controlled, or sponsored by, with, or on behalf of any respondent or by any supplier or manufacturer of the product. Also, the published report must provide sufficient information about the test for experts in the relevant

field to assess the reliability of the results.

*Provision X* mandates that respondents acknowledge receipt of the order, distribute the order to principals, officers, and certain employees and agents, and obtain signed acknowledgments from them.

*Provision XI* requires that respondents submit compliance reports to the FTC 60 days after the order's issuance and submit notifications when certain events occur for 10 years.

*Provision XII* requires that respondents create and retain certain records for 10 years.

*Provision XIII* provides for the FTC's continued compliance monitoring of respondents' activities during the order's effective dates.

*Provision XIV* requires that respondents notify their licensees, monitor their highest-selling licensees' advertising to ensure compliance with Provisions I through III, and suspend any licensee who makes any prohibited claims. Respondents must terminate any licensee who continues to make prohibited claims. There are two limited exceptions to the monitoring requirement: (1) Representations during private consultations between a licensee and one of the licensee's patients about the potential safety, health benefits, performance, efficacy, or side effects of a covered product; and (2) representations about the potential safety, health benefits, performance, efficacy, or side effects of a covered product by a licensee who has purchased a covered product solely for incorporation into the licensee's own product and markets that product without any involvement by respondents.

*Provision XV* requires that respondents send a notice to all customers who purchased directly from them TA-65MD or TA-65 Skin within one year prior to the issuance of the order or through a currently active enrollment in a continuity or autoshop program.

*Provision XVI* provides that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

**Donald S. Clark,**  
Secretary.

[FR Doc. 2018-04025 Filed 2-27-18; 8:45 am]

**BILLING CODE 6750-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Request for Information Regarding Patient-Reported Outcome Measures

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for information.

**SUMMARY:** AHRQ is seeking information submissions from the public.

Information is being solicited to inform our work on patient-reported outcomes (PROs). Access to information regarding physical function PRO measure use will assist the selection of measures for AHRQ's efforts to develop and implement user-friendly technical tools to collect and integrate PRO data in electronic health records or other health information technology products.

**DATES:** Submission must be received by April 1, 2018.

**ADDRESSES:** Electronic responses are preferred and should be addressed to [Janey.hsiao@ahrq.hhs.gov](mailto:Janey.hsiao@ahrq.hhs.gov). Non-electronic responses will also be accepted. Please mail to: Janey Hsiao, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, Mailstop: 06E73A.

**FOR FURTHER INFORMATION CONTACT:** Janey Hsiao, Health Scientist Administrator, Center for Evidence and Practice Improvement, [Janey.hsiao@ahrq.hhs.gov](mailto:Janey.hsiao@ahrq.hhs.gov), (301) 427-1335.

**SUPPLEMENTARY INFORMATION:** AHRQ plans to conduct a Challenge Competition in Fall 2018 to develop user-friendly technical tools to collect and integrate patient-reported outcome (PRO) data in electronic health records or other health information technology products. The technical tools will be intended for use in ambulatory care settings including primary care and specialty care. For this competition, AHRQ will choose a physical function PRO measure as a use case for the tool development. More information about the Challenge Competition is available at <https://www.gpo.gov/fdsys/pkg/FR-2017-12-26/pdf/2017-27663.pdf>. AHRQ will also conduct another project to pilot test whether the specified standards used in the Challenge Competition can be adapted for data collection utilizing other PRO measures or domains. AHRQ is interested in learning what physical function PRO measures are being used, and about experiences with these measures in clinical practice. We are also interested in methods used to collect these PROs, including computer adaptive testing