



United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of
Advertising Practices

July 11, 2024

Via FedEx and Email

Dr. Yudara Kularathne & Ms. Mei-Ling Lu
HeHealth Inc.
HeHealth Pte Ltd.
718 Pine Street
San Francisco, CA 94108

Dear Dr. Kularathne and Ms. Lu:

Following the March 2024 launch of HeHealth Inc.'s ("HeHealth") AI-powered sexually-transmitted infection ("STI") detection application, Calmara, FTC staff had concerns that the company's marketing materials may have overstated the extent to which Calmara could detect STIs. The Calmara application is targeted to consumers seeking "clarity" about their sexual partners' STI status "on the spot." Among other things, HeHealth has claimed that its Calmara application: (1) has up to a 94.4 percent accuracy rate for detecting 10+ conditions, including syphilis, herpes, and HPV; (2) provides consumers "clear, science-backed answers about your partner's sexual health status"; and (3) "flip[s] the script on those 3 a.m. 'What if?' spirals. No waiting. No guessing."

The FTC requires companies to have competent and reliable *scientific* evidence when making health-related claims.¹ The substantiation for HeHealth's ad claims that existed at the time the claims were made appears to be problematic for several reasons. As HeHealth's principal study conceded, (1) the data HeHealth used to test and train the AI detection model included images uploaded by individuals who were never subjected to diagnostic tests (e.g., "microbiologic or histologic testing") to confirm whether the individual associated with the image did in fact have an STI or not, (2) "the performance of the model was assessed on a relatively small number of images, limiting the precision of [the] findings," and (3) four of the five authors of the study either worked for HeHealth or were paid consultants.² In addition, staff had concerns that an individual with an asymptomatic STI would be far less likely to have accurate results because the AI was trained to detect visual symptoms like marks or lesions. Finally, according to the principal study,

¹ See, e.g., Notice of Penalty Offenses Concerning Substantiation of Product Claims, https://www.ftc.gov/system/files/ftc_gov/pdf/Substantiation-NPO.pdf.

² Lao-Tzu Allan-Blitz, et al., *The Development and Performance of a Machine-Learning Based Mobile Platform for Visually Determining the Etiology of Penile Pathology* (2024).

the AI was trained and assessed to detect 4 STIs, but Calmara claims to detect 10 or more conditions.

Consequently, on June 10, 2024, the FTC issued a civil investigative demand (“CID”) to HeHealth identifying concerns related to its advertising claims regarding Calmara and seeking, among other things, information about the company’s substantiation for Calmara’s accuracy claims. Staff also sought information about the company’s privacy practices, given the sensitivity of the images and information provided by consumers and Calmara’s advertising claims about maintaining anonymity with respect to the subjects of the images. In addition, on June 11, 2024, staff directed a Notice of Penalty Offenses (“NPO”) Concerning Substantiation of Product Claims to HeHealth, putting the company on notice that it is an unlawful act or practice to, among other things, “make claims relating to the health benefits or safety features of a product without possessing and relying upon competent and reliable scientific evidence that has been conducted and evaluated in an objective manner by qualified persons and that is generally accepted in the profession to yield accurate and reliable results, to substantiate that the claim is true.”³

We have reviewed the information you provided during, and subsequent to, our calls on July 3, July 8, and July 9, 2024, including your letter to staff confirming that HeHealth and its executives: (1) received and reviewed the FTC’s NPO; (2) will terminate the HeHealth and Calmara STI detection applications and remove all related advertising claims by July 15, 2024; (3) will refund all U.S. customers with unfulfilled Calmara purchases who have responded to HeHealth’s refund notice by July 15, 2024; and (4) will delete all customer personal information obtained through the HeHealth and Calmara applications by July 15, 2024, delete customer personal information obtained or accessed through its payment vendor by July 15, 2024, and request that its payment vendor delete any personal information of HeHealth or Calmara customers as soon as the vendor is legally able to do so. Pursuant to our discussions, your letter further stated that if the company or any future company controlled by either of its founders, now serving as the CEO and COO, including in their individual capacity, releases a similar product in the future, neither the companies nor the founders will make any misrepresentations about the product’s ability to accurately detect medical conditions.

Based upon these actions and other factors, including the small number of Calmara users and sales in the U.S., staff has decided not to pursue this investigation any further. We expect HeHealth and its founders to maintain this commitment as they develop future products for consumers.

The closing of this investigation is not to be construed as a determination that a violation may not have occurred, just as the pendency of an investigation should not be construed as a determination that a violation has occurred. The Commission reserves the right to take such further action as the public interest may require.

³ Continued or future engagement in the unlawful acts or practices outlined in the Notice of Penalty Offenses Concerning Substantiation of Product Claims could subject the company and its leadership to civil penalties of up to \$51,744 per violation.

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If you have any further questions, please do not hesitate to call Michelle Rosenthal (202-326-2616) or Naomi Takagi (202-326-3668).

Sincerely,

A handwritten signature in black ink that reads "Serena Viswanathan" with a long horizontal flourish extending to the right.

Serena Viswanathan
Associate Director
Division of Advertising Practices