Challenger:

Monitoring

#### **BASIS OF INQUIRY**

Direct response advertising for the iRenew Bracelet, marketed by the Harvest Trading Group, came to the attention of the Electronic Retailing Self-Regulation Program ("ERSP") through its self-monitoring program. ERSP inquired about several representations regarding product performance that were disseminated in broadcast and online advertising, including the following claims:

#### Performance Claims

- "Renew Strength; Renew Energy"
- "The revolutionary bracelet that uses natural frequencies to promote strength and wellness"; "Every iRenew bracelet is programmed with natural frequencies that your body positively responds to."
- *"Feel the difference immediately!"; "Experience the results the moment you begin using the iRenew Balance System products"*
- "iRenew is the newest, most powerful energy balancing technology available today!"
- "May promote strength; may promote balance; may promote endurance"
- *"iRenew Energy Balance System Products with BioField Technology Work To Rebalance Your BioField"*

#### Establishment Claims

- *"iRenew biofield therapy products with BioField Technology utilize a proprietary quantum based technology to harness the natural frequencies which are ever present in our environment and use them to tune and rebalance your biofield back to a more natural, coherent state."*
- *"iRenew's proprietary, nano-based BioField Technology not only improves the biofields of people but also can positively impact anything biological which includes the biofields of plants and animals as well."*

### Consumer/Testimonials

- "I have worn the bracelet for several weeks and I can truthfully say that I believe I generally feel better and have a higher energy level." [Mike]
- "Since I have been wearing the bracelet, I have noticed a dramatic decrease in joint and muscle pain, as well as headaches associated with neck pain. Normally, by the end of a busy/stressful day I have significant pain in my neck and lower back. However, since I have been wearing the I-Renew, the pain has nearly stopped completely."[Joy]
- "The most persistent ache being carpel tunnel in my left wrist... I noticed that not only had the pain in my wrist subsided but I was sleeping better at night... happy to say no more carpal tunnel." [Sha Lopez]

- "I have stage 4 rectal cancer which is giving me a fight for my life. Today I walked 10 blocks and I haven't walked in weeks because I haven't felt up to it. I know it is the bracelet! I can't believe it!" [Sherry]
- "After wearing this bracelet for only a few minutes, I noticed the pain in my hand and wrists went away while I was writing and to top that off, a little while later I notice my ankle stopped bothering me and of course we all know the head ache and eye pain we all get from staring at the computer for to long, well that went away too." [Chris Hernandez]
- "My son is a 15 year old male with diagnosis of Autism, Neuroimmune Dysregulation (allergies, viral, elevated HHV6 titers), scoliosis, mild mental retardation. After having Greyson wear the iRenew bracelet for 1 week he became brighter eyed, more engaged, a sense of calm, shorter/quicker response time in communicating, a good week at school (this has been the norm for him thus far), Speech Therapist reported improvement since she last saw him 2 weeks ago. Finally made improvement from what he had been working on for weeks. OT reported more stamina, more attending to the task. We are impressed and very happy about his improved condition." [Lisa]
- "I noticed that I sleep through the night like a baby."
- "iRenew makes me stronger and more flexible."
- *"FMS/CFS arthritis.. to name just a few things ..Chronic pain has been a way of life Allergic to all pain meds except tylenol..two weeks with this on I now have very little pain!! Some days none at all."* [Patti Durant from Facebook]

### Expert Testimonial

• "Once you balance your body's energy with iRenew, you balance your overall health." [Scott Becker, MD]

Additionally, in light of the Federal Trade Commission's revised *Guides Concerning the Use of Endorsements and Testimonials in Advertising* (<u>http://www.ftc.gov/opa/2009/10/endortest.shtm</u>)</u> which went into effect

December 2009, ERSP expressed its concern with the omission of material information in the advertising regarding the generally expected product performance.

### **MARKETER'S POSITION**

After commencement of the self-regulatory inquiry, Harvest Trading Group informed ERSP that the broadcast advertising at issue had run its course and was in the process of being withdrawn. However, it advised ERSP that several of the claims at issue would continue to be made in future advertising, albeit in a less categorical and different context. As such, the marketer provided ERSP with its evidentiary support for the core claims at issue as well as a detailed analysis of the product's mechanism of action.

### 1. Mechanism of Action

The marketer explained that the iRenew bracelet is constructed and energized so that the wearer feels and experiences the same electromagnetic field frequencies that are used to activate the bracelet. The iRenew bracelet is made of 100% silicone rubber and stainless steel and according the Harvest Trading Group, both are hypoallergenic and safe for use. The marketer stated that the engineered structure offers a unique combination of chemical properties, such as silicon dioxide

content which is known to be hygroscopic, readily absorbing water from the air. The Harvest Trading Group maintained that for these basic reasons, silicone rubber (white or black) is ideal to be infused with the company's Selective Frequency Resonance (SFR) technology.

The marketer explained that the science behind SFR efficacy is that contained water with an electromagnetic field is known to store information that biological systems can "*read*" and, furthermore, respond to as if they were exposed to the original electromagnetic field. Water is also structured in the sense that it has quantum coherent domain properties that are expected to be sensitive to external electromagnetic fields.

Both the silicone and the stainless steel in the bracelets are subjected to the proprietary high voltage SFR filtering process to create solid-state resonance with selective frequencies that are biocompatible, referred to as *"bioinformation"* or *"bioscalars."* Furthermore, the marketer asserted, the structural components of the bracelets are electromagnetically modulated from a mix of Hertzian and non-Hertzian waves produced by the energizing process of SFR.

According to the Harvest Trading Group, the bracelet's stainless steel was also chosen because rather than plastic or other non-metallic material, it has a beneficial effect on the skin's free radical quenching, epidermal homeostasis and permeability barrier recovery. The marketer also noted that the iRenew activation process vibrates the molecules of the composite bracelet substrate, unfolding the lattice structure by application of simultaneous high voltage, thus alerting the atomic structure of the bracelet, which then collapses back as the high voltage is turned off, which traps the bioinformation.

The Harvest Trading Group stated that the iRenew bracelet is worn on either the left or right wrist. Being in close proximity to the iRenew bracelet allows its stored bio-information to affect a biological system in a beneficial manner, mainly because of its quantum coherence effect. The marketer contended that the studies summarized below demonstrate, among other things: that DNA exhibits increased electrical conductivity in the presence of the bracelet which has favorable implications for the repair of damaged DNA; an 80% significant improvement in balance; water droplets exhibit a lowered surface tension when in proximity to the iRenew bracelet; and, shocked bacteria recover faster in the presence of the bracelet which has beneficial implications for the human colon and biological regulation. Additionally, a white paper was submitted by the Harvest Trading Group showing that the reinforcement of the biofield by a *passive resonating frequency product* worn next to the skin can strengthen the body's ability to self-regulate and perform optimally under external or internal stressors, optimizing appropriate specific function and stability.

### 2. Clinical Studies

### A. The Southwestern Oklahoma State University Study

As noted above, the Harvest Trading Group indicated that the technology utilized in iRenew products is based upon electromagnetic and bioenergy principles. The iRenew bracelet was the subject of a clinical study that directly tested the product on 100 subjects. The double-blind, placebo controlled study was conducted at Southwestern Oklahoma State University ("The SWOSU study") and included male and female adult volunteer subjects from the university and surrounding fitness centers.

Each subject completed two tests – the Balance Error Scoring System ("BESS") and the Bench Press Endurance test ("BPET"), a widely used test of anaerobic capacity and strength. The subjects completed test two times each, one time with the iRenew bracelet and one time with a placebo bracelet. Neither the subjects nor the physical trainers gathering data knew whether the bracelet being worn was the iRenew bracelet or placebo.

When taking the BESS test, subjects were instructed to assume a particular position on a foam pad and maintain that position during six, 20-second trials, with each trial involving a different position. For each test subject, a trainer observed the subject and recorded any errors (i.e., deviations from the proper stance) that the trainer observed.

Each 20-second trial was scored by counting the number of recorded errors. The mean number of balance errors that the subjects experienced while wearing the iRenew bracelet was 6.38, whereas the mean number of balance errors for the placebo bracelet 32.94, indicating an 80.6% decrease in the average balance errors subjects committed while wearing the iRenew bracelet as compared to the placebo bracelet.

With respect to BPET, subjects were instructed to complete as many bench presses as they could. The weight selected for each subject was based on the subject's weight and estimated strength level, using information provided by the subjects. The subjects were instructed through visual demonstration with regard to the proper technique for bench presses. Results of the BPET showed that subjects averaged 11.68 bench presses while wearing iRenew and 10.06 presses while wearing the placebo, a 16.1% difference.

### B. Human DNA Study

According to Harvest Trading Group, numerous studies have demonstrated that the DNA molecule is highly sensitive to electromagnetic (EM) fields and therefore can be used to test the hypothesis that activated iRenew bracelets emit some kind of EM field. In the DNA study, the electrical conductivity of DNA was measured because previous studies have shown that this particular property is extremely sensitive to ultra-weak DNA fields (expected to be emitted by the bracelet) and the electrical properties (e.g., conductivity) are well known to be correlated with DNA repair, protection and transcription processes that naturally occur in human cells.

In the experiments, a voltage (10mV, 28 kHz) was applied at one electrode and the current was measured at a second electrode using a standard, state-of-the-art potentiostat. The two electrodes were placed in a test tube containing purified human DNA. For controls, DNA was placed adjacent to the main metal part of a non-activated (control) bracelet for one hour. Separate samples of DNA were then placed adjacent to activated bracelets (as sold commercially) for one hour. Twenty-one separate control samples were measured and 31 separate treated samples were run.

The magnitude of the response and the probability (frequency of occurrence) were calculated since this, according to the marketer, is a dynamic system. The magnitude of the electrical response from DNA samples exposed to the untreated (control) bracelets was  $1.9 \pm 1.8$  and this response was observed 28% of the time. This is the expected response of DNA itself, which conducts electricity (somewhat) in response to the voltage stimulus used in this experiment. The magnitude of the electrical response increased to  $3.2 \pm 2.7$  when the DNA was placed adjacent to an activated bracelet and this response occurred 52% of the time. The overall effect was

statistically significant. Therefore, the Harvest Trading Group maintained, it can be concluded that an EM field is emitted from the activated bracelet, which enhances the electrical properties of DNA.

# 3. Pilot Studies

# A. Energy Medicine Research Institute Study

The Harvest Trading Group submitted a human pilot study that examined the efficacy of the iRenew bracelet to increase strength, balance and endurance on 14 healthy subjects. According to the marketer, the test demonstrated that the iRenew bracelet increased all of the aforementioned performance attributes.

The tests conducted included stretch and reach, hand strength and peak wattage per pound on a stationary bike during an endurance test. In the flexibility test (i.e., stretch and reach) results indicated that there was a nearly two-fold increase in the effect of the active bracelet versus the placebo compared to baseline. In the hand strength test, study administrators observed a decrease in the effect of the placebo bracelet versus a dramatic increase in the effect of the active bracelet.

In sum, the investigators concluded that the improvements in the effects of the active bracelet were greater than the placebo bracelet in every measure, with up to a greater than 6-fold increase in effects of active versus placebo bracelets.

# B. 2009 SWOSU Study

As a precursor to the larger scale SWOSU test described in paragraph "1(A)" above, a small pilot study was conducted in 2009 to determine if the iRenew had an effect on the performance of athletes through a range of balance, flexibility, endurance and strength tests. More specifically, six athletes were randomly picked to participate in seven recognized tests: the Balance Error Scoring System ("BESS"), 225 lbs. bench press repetitions, broad jump, push up endurance test, flexibility testing, pro agility drill and standing vertical leap. The athletes were tested in all seven areas prior to the introduction of the iRenew biofoield technology. The athletes were then asked to wear wristbands activated with the iRenew biofield technology in order to conduct the seven tests.

According to the Harvest Trading Group, the results of the study indicated that the iRenew bracelet improves balance in all directions by a substantial percentage. The endurance tests showed small increases and the iRenew biofield technology helped the athletes achieve better scores on all tests.

### C. Institute For Frontier Science (IFFS) Study

The marketer submitted a copy of a pilot study that was conducted to look for an effect on the growth and motility of heat-shocked *E.coli* bacterial cultures under controlled laboratory conditions. Two groups of bracelets, A and B, were used, and the researchers did not know which was the activated bracelet and which was the inactive control. After heat-shock treatment, a 1cm piece of bracelet consisting of stainless steel and silicone rubber was added aseptically to each of the 6 sample tubes (3 in each group). The samples were then incubated in two identical chambers maintained at 37 C in which growth was monitored continuously via a real-time

computerized data acquisition system. A plate count assay was performed 3 hours later. According to Harvest Trading Group, the data consistently showed that that Group B cultures grew significantly faster (13.7%) than Group A.

Following statistical analysis and submission of a preliminary report, the study was unblended and the test researchers learned that bracelet "B" was the activated iRenew bracelet. It was noted that although the iRenew bracelet is designed for humans, fields imprinted in the bracelet may also be beneficial to certain life functions in other organisms, especially in the presence of stressors. The most basic functions of life are growth and movement, both of which were studied in the IFFS study.

The marketer maintained that the study demonstrated that the iRenew bracelet was found to promote the recovery and growth of *E.coli* following heat-shock.

# D. Psy-Tek Labs study

The marketer provided ERSP with a report of a preliminary test of iRenew in water and around glass jars containing water. More specifically, the study evaluated the effect of the iRenew bracelet on distilled and Fiji water. The researchers noted that it was apparent that the reactions of the two waters to the bracelets were very different. The only significant effect on the distilled water was the average intensity, which was the only parameter that did not show a significant effect on the Fiji water. Harvest Trading Group contended that the fact that more parameters were changed for the Fiji water suggests that water with minerals is more responsive than distilled water.

# E. GDV Study

In 2009, the marketer conducted a one person study designed to measure the influence of iRenew's biofield technology on the human energy field.

The iRenew bracelet was worn on the right hand wrist for 10 minutes and then gas discharge visualization (GDV) data was captured. More specifically GDV technology is a breakthrough beyond traditional techniques (i.e., Kirlian photography) for direct, real-time viewing of the human energy field (biofield). This new technology allows one to capture, by special camera, the physical, emotional, mental and spiritual energy emanating to and from an individual, plants, liquids, powders, and inanimate objects.

According to the GDV data of this individual, the energy field increase between the individual test subject wearing and not wearing the bracelet was over 30%. The analysis also indicated that energy field increase was greater on the left side of the body (40%) than on the right side (15%).

# F. Nutritional Microscopy Test

In 2009, 10 subjects participated in a nutritional microscopy test that evaluated the effects of iRenew's biofield technology on the metabolic dysfunction of live blood cells. By observing the blood through a high-powered microscope, the microscopist and client are able to detect the overall health of the cells. When the blood cells are healthy, the body has more energy and the cells are less challenged by acid and indications of related symptomologies. The marketer added that it is well recognized that blood shows biological changes when the body is experiencing

symptoms of sickness and disease. It has been discovered that certain blood profiles are associated with certain health challenges.

Overall, the subjects that were subjected to the iRenew bracelet reported higher energy levels and stamina after 1 week of wearing the iRenew bracelet. The Harvest Trading Group maintained that the results (i.e., blood work) show healthier cells. Collectively, the studied cells were uniform in size and shape, residing in clearer plasma, mostly free of debris, and gently repelling off each other due to negative charge. These are all indications of a cell in a healthier, more homeostatic state.

# 4. Performance Attributes

# Promotes Balance

The marketer maintained that the double-blind, placebo controlled SWOSU study demonstrates that the iRenew bracelet can promote balance in users, as it directly tested the iRenew product's effect on subjects' balance through a widely used balance test, the results of which, show a very significant decrease in the average number of balance errors committed by subjects when using iRenew as compared to placebo.

# Promote Endurance

The marketer further contended that the SWOSU study demonstrated, by virtue of the BPET test, that the iRenew bracelet can promote endurance. On average, the subjects in the SWOSU study who were instructed on proper bench pressing technique performed 16.1% more bench presses while using the iRenew than when using a placebo bracelet.

The Harvest Trading Group noted that the endurance-promoting abilities may be due in part to its effectiveness in promoting balance. Proper physical balance facilitates the performance of physical tasks and allows for more efficient execution of such tasks. The marketer asserted that it is widely accepted that the better balance a person has in performing a physical task, the less energy a person must expend to perform the activity. By promoting balance, iRenew may help a person perform a physical task more efficiently, leading to a decrease in energy expenditure while performing the task. This may increase the duration in which a person can engage in physical exertion.

# Promote Strength

The marketer again referred ERSP to the SWOSU study which measured the number of times subjects could perform a bench press using iRenew as compared to placebo. The weight selected for the bench press test depended on each subject's body weight and estimated strength level. Among 100 test subjects, the average number of bench presses increased by a mean of 16.1% while using iRenew as compared to placebo.

iRenew's ability to promote strength may be attributable partly to its ability to promote balance. The symbiotic relationship between balance and strength is well-established. Physical stability contributes to muscle resistance performance (i.e., resistance to the force of muscular contraction) and aids a person in supporting and propelling weight, as does the foundation of any

physical structure. By promoting balance, iRenew may help a person resist weight, thereby promoting strength.

# ADMINISTRATIVE DETERMINATION AND ANALYSIS

Shortly after initiating the self-regulatory inquiry, ERSP was informed by the marketer that the broadcast and online advertising for the product were being phased out and that the claims at issue were being discontinued. However, because the Harvest Trading Group advised ERSP that it planned on disseminating several limited, less categorical performance claims in future advertising with respect to strength, balance and endurance ERSP thought it useful to continue with its evaluation of the marketer's evidence as it pertained to future performance representations in a qualified context.

In the past several years, various energy bracelets have been the subject of regulatory scrutiny based upon unsupported claims that were being disseminated regarding the product's ability to provide both specific and general health benefits to consumers. For example, in 2004, marketers of the *"Balance Bracelet,"* a purported pain relief product, agreed to settle charges with the Federal Trade Commission (FTC) with respect to direct response advertising that claimed that the Balance Bracelet is a fast-acting, effective treatment for many types of pain.

Moreover, in 2006 a federal district court in Chicago ruled for the FTC in its case against the marketers of the Q-Ray ionized bracelet, finding that the marketer's advertising falsely represented that the Q-Ray bracelet provided immediate, significant, and/or complete pain relief, and that scientific tests proved that it relieved pain. In a recent January 2011 non-regulatory review, researchers from the Discipline of Chiropractic in The Royal Melbourne Institute of Technology (RMIT) School of Health Sciences conducted a randomized, double-blind trial of 42 subjects, and found that Power Balance wristbands have no effect on balance and stability. Power Balance bracelets contain a hologram embedded with frequencies that react positively with your body's energy field to improve your balance, strength, flexibility, energy, and sports performance.

In this case, unlike the Power Balance bracelet, the iRenew bracelet does not contain an embedded hologram that triggers its mechanism of action, although it does utilize electromagnetic field frequencies that are used to activate the bracelet. In addition, unlike the advertising for the Q-Ray and Balance bracelets, future advertising for the iRenew bracelet will not contain any health claims or representations regarding the ability of the bracelet to eliminate or alleviate pain.

Moreover, the Harvest Trading Group has assured ERSP that it has discontinued any absolute, unqualified representations of product performance communicated either expressly by the spokesperson featured in the advertising or in consumer testimonials featured therein. Further, the marketer has indicated to ERSP that the demonstration used in the infomercial to show that wearing the iRenew bracelet will improve balance has been discontinued and will no longer be used in any future advertising.

The marketer has represented that future claims for the iRenew bracelet will be qualified with language it believes is consistent with the evidence submitted; for example, that the bracelet *"may promote"* strength, endurance and balance. Generally, with respect to claims that a product *"promotes"* or *"supports"* a particular performance attribute, the burden is on the marketer to

show that the product (or an ingredient contained therein) has been demonstrated to contribute to the performance benefit claimed.

For example, in May 2009, the National Advertising Division of the Council of Better Business Bureaus, Inc. ("NAD") reviewed advertising claims for Hill's Pet Nutrition's *Science Diet Healthy Development Puppy and Kitten Foods*. Among the claims disseminated in the advertising were that Healthy Development Puppy food has "*tested nutrition to promote healthy joint development*." In its analysis, NAD determined that the plain meaning of "promoting" healthy joint development is that the product "*contributes to the progress or growth*" of healthy joints, a message it found supported because of evidence showing the high levels of DHA and EPA in the blood serum of puppies fed the Science Diet.

Accordingly, ERSP determined that the guidance provided by NAD is particularly relevant to the subject inquiry and agreed that if the marketer intended to use claims in future advertising stating that the iRenew "*may promote*" strength, endurance and balance, it would be incumbent on the Harvest Trading Group to demonstrate and possess evidence showing that the product "*may contribute*" to the improvement of these specific performance characteristics.

Although there is existing uncertainty regarding the utilization of electromagnetic fields to provide tangible performance benefits, it is also widely accepted that low-frequency electric fields influence the human body just as they influence any other material made up of charged particles. For example, when electric fields act on conductive materials, they influence the distribution of electric charges at their surface. Low-frequency magnetic fields induce circulating currents within the human body. The strength of these currents depends on the intensity of the outside magnetic field. If sufficiently large, these currents could cause stimulation of nerves and muscles or affect other biological processes.

Both electric and magnetic fields induce voltages and currents in the body, but, even directly beneath a high voltage transmission line, the induced currents are very small when compared to thresholds for producing shock and other electrical effects. Moreover, according to the World Health Organization ("WHO"), approximately 25,000 articles have been published over the past 30 years in the area of biological effects and medical applications of non-ionizing radiation, with much of the effort currently being directed towards the study of electromagnetic fields in relation to cancer.

Unlike the inquiries pertaining to hologram bracelets in which there has been little or no testing produced to support claims (many of which involved express health benefits), the Harvest Trading Group has produced a number of studies to ERSP documenting the potential effect of the iRenew bracelet, most notably a double-blind clinical study that directly tested the product on 100 subjects at Southwestern Oklahoma State University.

The SWOSU study involved both balance and endurance tests. The BESS test is an industry accepted test developed as a standardized, objective assessment tool for the clinical sideline assessment of postural control. The primary objective of the BESS is to provide clinicians with an immediate measure of postural control when assessing a patient with a potential MHI during a sideline clinical evaluation. As noted in the marketer's position, the mean number of balance errors that the subjects experienced while wearing the iRenew bracelet was significantly lower than the mean number of balance errors for the placebo bracelet.

Similarly, the bench press component of the study was designed to measure the test subject's anaerobic capacity and the test has long been an accepted method of evaluating strength and endurance. Increased strength is readily ascertainable as subjects were instructed to simply complete as many bench presses as they could. The results of the study showed a 16.1% difference in the number of repetitions before and after using the iRenew bracelet.

The SWOSU study was conducted because of the encouraging results of a number of in-vitro and in-vivo pilot studies either the iRenew bracelet itself or components thereof. The Harvest Trading Group also advised ERSP that it is currently undertaking another large scale study of the iRenew bracelet that it hopes will further corroborate the findings of the 2010 SWOSU study.

Notwithstanding the ongoing testing, ERSP would be remiss in not recognizing that the marketer has made a concerted effort to discontinue many of the aggressive representations communicated in the original broadcast advertising and further, it has dramatically modified its online advertising (e.g., <u>www.buyirenew.com</u> and <u>www.BuyiRenewBracelet.com</u>) by eliminating streaming video of the original short-form broadcast advertising as well as consumer testimonials attesting to the performance benefits of the product.

It has come to the attention of ERSP that the marketer plans to use consumer testimonials in future broadcast advertising in a limited, non-categorical context (i.e., "*may improve*" strength, balance and endurance) that is consistent with its testing. Based upon the evidence provided by the marketer, ERSP does not object to such representations, but cautions the Harvest Trading Group that such testimonials must be consistent with the FTC's *Guides Concerning the Use of Endorsements and Testimonials in Advertising*, specifically, section 255.2(b).

### CONCLUSION

The Harvest Trading Group has advised ERSP that the advertising that was the subject of this inquiry has been permanently discontinued and that the marketer has no intent of using the same claims or demonstration in any future advertising for the iRenew bracelet. Notwithstanding this representation, the marketer informed ERSP that it would continue to disseminate limited, qualified performance claims based upon existing testing on the product and the existing science of low-frequency electromagnetic fields. Based upon the collective evidence provided by the marketer, ERSP determined that such representations would not be inaccurate so long as the claims are communicated in an appropriate context.

### **MARKETER'S STATEMENT**

"Harvest Direct appreciates the opportunity to participate in the Electronic Retailing Self-Regulation Program's ("ERSP") self-regulatory process. We are pleased ERSP determined that clinical studies and other scientific literature demonstrate that iRenew may promote strength, endurance, and balance.

Harvest Direct is committed to ensuring that its advertising is truthful, accurate, and substantiated. We value and support industry self-regulation and welcome the ERSP's decision regarding advertising for iRenew."

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