DA 22-920

Before the Federal Communications Commission Washington, D.C. 20554

In the Matter of	
Health and Medical Sales, Inc. dba	
HealthandMed.com	

File No.: EB-SED-19-00029853

CITATION AND ORDER ILLEGAL MARKETING OF UNAUTHORIZED RADIO FREQUENCY DEVICES

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Adopted: September 2, 2022

By the Chief, Spectrum Enforcement Division, Enforcement Bureau:

I. NOTICE OF CITATION

1. This **CITATION AND ORDER** (Citation), notifies Health and Medical Sales, Inc. dba HealthandMed.com ("Health and Med" or "Company") that it unlawfully marketed¹ radio frequency devices in the United States in violation of the Commission's equipment authorization requirements. Specifically, Health and Med marketed the 14 models identified in the attached Appendix without obtaining an authorization in violation of section 302(b) of the Communications Act, as amended (Act), and section 2.803(b) of the Commission's rules.² We therefore direct Health and Med to comply with the Commission's equipment authorization requirements for these devices, and to cease any marketing of unauthorized radio frequency devices in the United States. If Health and Med fails to comply with these laws, it may be liable for significant fines of up to \$22,021 per day for each model marketed, as well as other sanctions.³

2. Notice of Duty to Comply with the Law: We issue this Citation pursuant to section 503(b)(5) of the Act, which states that the Commission may not impose monetary forfeitures against non-regulatees who violate Commission rules or the Act unless and until: (a) the Commission issues a citation to the violator; (b) the Commission provides the violator a reasonable opportunity to respond; and (c) the violator subsequently engages in conduct described in the citation.⁴ Accordingly, Health and Med is hereby on notice that it must comply with section 302(b) of the Act and section 2.803 of the Commission's rules and applicable rules in parts 2, 15 and/or 18.⁵ If Health and Med subsequently engages in any conduct of the type this Citation describes – and specifically any violation of section 302(b) of the Act and section 2.803 of the Commission's rules and applicable rules in parts 2, 15 and/or 18.⁵ If Health and Med subsequently engages in any conduct of the type this Citation describes – and specifically any violation of section 302(b) of the Act and section 2.803 of the Commission's rules and applicable rules in parts 2, 15 and/or 18.⁵ If Health and Med subsequently engages in any conduct of the type this Citation describes – and specifically any violation of section 302(b) of the Act and section 2.803 of the Commission's rules and applicable rules in parts 2, 15 and/or 18 – it may be subject to civil penalties, including but not limited to, substantial monetary forfeitures. In

⁴ See 47 U.S.C § 503(b)(5).

Released: September 2, 2022

¹ 47 CFR § 2.803(a) (defining marketing as the "sale or lease, or offering for sale of lease, including advertising for sale or lease, or importation, shipment or distribution for the purpose of selling or leasing or offering for sale or lease.").

² 47 U.S.C. § 302a(b); 47 CFR § 2.803(b). The Appendix also lists models for which the Enforcement Bureau seeks additional information to confirm compliance. As explained herein, these devices must be authorized under either part 15 or part 18 of the Commission's rules, both of which would typically require either certification or Supplier's Declaration of Conformity authorization.

³ See 47 U.S.C. § 503(b)(2)(D); 47 CFR § 1.80(b)(9); Amendment of Section 1.80(b) of the Commission's Rules, Adjustment of Civil Monetary Penalties to Reflect Inflation, Order, DA 21-1631, 87 Fed. Reg. 396 (Jan. 5, 2022).

⁵ 47 U.S.C. § 302a(b); 47 CFR § 2.803. Health and Med must also ensure all applicable labeling and user manual requirements are met as well in parts 2, 15, and/or 18 of the Commission's rules. *See e.g.*, 47 CFR §§ 2.925, 2.926, 2.1074, 2.1077, 15.19, 15.21, 18.209, 18.212, 18.213.

assessing such forfeitures, the Commission may consider both the conduct that led to this Citation and the conduct following it.⁶ Health and Med should take immediate steps to ensure that all radio frequency equipment in its inventory that is marketed to U.S. consumers is authorized for sale in the United States and compliant with all applicable rules.

3. *Notice of Duty to Provide Information*: Pursuant to sections 4(i), 4(j), and 403 of the Act,⁷ we direct Health and Med to respond in writing, within 30 calendar days after the release date of this Citation, to the questions and requests for documents set out in paragraph 12, below.

II. BACKGROUND

4. <u>Legal Background</u>. To best accommodate the diversity of radio communication needs, the Commission partitions radio frequency spectrum, and creates different radio services, each with different operating parameters. The Commission also implements an equipment authorization process designed to ensure that radio frequency devices that intentionally emit radio waves meet various operating requirements, including power levels, frequency, and channel bandwidth.⁸ Unintentional radiators, devices that by design use digital logic, or electrical signals operating at radio frequencies for use within the product, or send radio frequency signals by conduction to associated equipment via connecting wiring, but are not intended to emit radio frequency energy wirelessly by radiation or induction must be authorized prior to the initiation of marketing under part 15 of the Commission's rules.⁹ Finally, electronic products used for providing radio frequency energy for Industrial Scientific and Medical (ISM) purposes are authorized under a different set of rules in part 18 of the Commission's rules.¹⁰

5. The Commission has two equipment authorization procedures: (1) Certification and (2) Supplier's Declaration of Conformity (SDoC).¹¹ Certification is an equipment authorization, using a third-party FCC-recognized Telecommunication Certification Body (TCB), based on an evaluation of supporting documentation and test data contained in an application submitted by the responsible party (e.g., the manufacturer or importer) to the TCB.¹² Compliance testing for certification is performed by an FCC-recognized accredited testing laboratory.

6. For devices subject to SDoC, a compliance information statement that includes the following items must be supplied with the product at the time of marketing or importation: Identification of the product, e.g., trade name, model, etc., a statement that the product complies with the rules, as applicable;¹³ and the name and address, and telephone number, or internet contact information of the responsible party's contact located in the United States.¹⁴ Each device is also subject to labeling

⁶ See S. Rep. No. 95-580, 95th Cong., 1st Sess. at 9 (1977) (If a person or entity that has been issued a citation by the Commission thereafter engages in the conduct for which the citation of violation was sent, the subsequent notice of apparent liability "would attach not only for the conduct occurring subsequently *but also for the conduct for which the citation was originally sent.*") (emphasis added).

⁷ 47 U.S.C. §§ 154(i), 154(j), 403.

⁸ 47 CFR § 2.907.

⁹ 47 CFR §§ 15.3(z), 15.101.

¹⁰ 47 CFR pt. 18.

¹¹ 47 CFR §§ 2.906, 2.907.

¹² 47 CFR § 2.907.

¹³ See 47 47 CFR §§ 2.1074 and 2.1077. For devices subject to part 15 and 18 rules, the statements required in sections 15.19(a)(3) and 18.212, respectively meet the requirements of this rule part. FCC, Office of Engineering and Technology, KDB 784748 D01 General labeling and Notification v09r01, https://apps.fcc.gov/kdb/GetAttachment.html?id=tz8CzcfpIVA2%2BognLZYTgA%3D%3D (July 2, 2018).

¹⁴ 47 CFR §§ 2.909(b), 2.1077.

requirements based on the equipment authorization procedure prescribed in the specific FCC rules that apply to the product.¹⁵

7. Unintentional radiators under part 15 shall be authorized prior to the initiation of marketing, pursuant to the procedures for certification or SDoC.¹⁶ Similarly, the Commission's rules for consumer ISM equipment under part 18 state that the equipment "must be authorized under either the Supplier's Declaration of Conformity or the certification procedure prior to use or marketing."¹⁷ Furthermore, under part 18, "[c]onsumer ultrasonic equipment generating less than 500 watts and operating below 90 kHz, and non-consumer ISM equipment shall be subject to Supplier's Declaration of Conformity."¹⁸

8. <u>Factual Background</u>. Health and Med is a Utah-based company that sells wellness products through its website HealthandMed.com, including ionic, detoxing footbaths.¹⁹ The Commission received a complaint regarding Health and Med's marketing of radio frequency equipment, specifically the IonizeME Maxx ionizing footbath, without a proper part 18 authorization. The Spectrum Enforcement Division (the Division) observed that the ionic footbath models marketed on the Health and Med website have digital displays, use digital power supplies, and have other indicia that they are unintentional radiators or ISM devices, either of which require an authorization prior to marketing.²⁰ In response to the Division's Letter of Inquiry (LOI),²¹ Health and Med stated that it sold 14 models of ionizing footbaths. Health and Med provided the dates for which sales commenced for each model of footbath sold. The Company admits sales of the 14 models began "before 2018," with sale ending dates ranging from 2018 through August 27, 2020. Health and Med admits that sales during this time took place without first obtaining the appropriate equipment authorization.²²

9. Health and Med argued that the devices were not radio frequency equipment and that neither the manufacturers nor the suppliers believed the equipment was subject to FCC rules.²³ In response to additional inquiries from the Division, the Company had the IonizeME Maxx, the IonizeME Maxx Dual, and the IonizeME Maxx Go tested under part 15, subpart B of the Commission's rules as unintentional radiators. The Company reported that these models passed the tests.²⁴ The tests were performed to measure the radio frequency energy produced by the devices. Test reports show that the devices emitted radio frequency energy (conducted and radiated).²⁵ The Company informed the Division

17 47 CFR § 18.203(a).

18 47 CFR § 18.203(b).

¹⁹ Health and Med, About Us, healthandmed.com/pages/about-us (last visited Aug. 26, 2022).

²⁰ 47 CFR §§ 2.803 (authorization required prior to marketing), 15.3(z) (unintentional radiator), 15.101 (authorization required for unintentional radiator), 18.107(c) (ISM devices), 18.203 (authorization required for ISM devices).

²¹ Letter of Inquiry from JoAnn Lucanik, Deputy Chief, Spectrum Enforcement Division, FCC Enforcement Bureau, to Mark Axelson, President, Health and Medical Sales, Inc. (January 14, 2020) (on file in EB-SED-19-00029853).

²² Response to LOI at 3-4, Response to Question 12 (Feb. 14, 2020); Response to Supplemental LOI from Mark Axelson, President, Health and Medical Sales, Inc,) Jane Kelly, Attorney, Enforcement Bureau, FCC at 3-5, Response to Inquiry 2 (June 3, 2020) (Response to Supplemental LOI) (on file in EB-SED-19-00029853).

²³ Id.

²⁴ Email from Mark Axelson to Jane Kelly, Spectrum Enforcement Division (Aug. 27, 2020) (on file in EB-SED-19-00029853).

²⁵ Id.

¹⁵ 47 CFR §§ 2.925, 2.1074, 15.19(a)(3)-(5), 18.209(b).

¹⁶ 47 CFR § 15.101.

that it discontinued the sale of other models to avoid testing expenses.²⁶ Subsequently, the Division observed that the Company continues to sell the IonizeME Touch and the IonizeMe Maxx 5, but has not yet provided information about the authorizations for those models.²⁷

III. APPLICABLE LAW AND VIOLATIONS

10. The Act and the Commission's rules require that most radio frequency devices be properly authorized, identified, and labeled before they can be marketed in the United States. Section 302(b) of the Act states that "[n]o person shall manufacture, import, sell, offer for sale, or ship devices or home electronic equipment and systems, or use devices, which fail to comply with regulations promulgated pursuant to this section."²⁸ Section 2.803(b) of the Commission's rules prohibits marketing devices unless they have been authorized in accordance with the Commission's technical standards and properly identified and labeled.²⁹

11. After examining the documentation Health and Med provided in response to the LOI, and its review of the Company's website, the Division determined that 14 of the models listed in the attached Appendix were not properly authorized prior to marketing on the Health and Med website. The test reports provided by the Company indicated that the devices were radio frequency devices that required authorization prior to marketing in the United States, which the Company did not have at the time.³⁰ Whether classified as part 15 unintentional radiators or part 18 ISM equipment, an authorization was required prior to marketing, and the Company admits it marketed at least fourteen models prior to any authorization.³¹ Accordingly, based upon the information before us, we find that Health and Med violated section 302(b) of the Act and section 2.803(b)(1) of the Commission's rules.³²

IV. REQUEST FOR INFORMATION

12. Additionally, we seek information on the other two models, the IonizeME Maxx 5 and the IonizeME Touch, to confirm they are properly authorized. We direct Health and Med to respond to the following inquiries and provide the requested documents within 30 days from the release date of this Citation:

- i. Provide copies of any equipment authorization or test reports for the IonizeME Maxx 5 and the IonizeME Touch.
- ii. Provide copies of the user manual and labeling for the IonizeME Maxx 5 and the IonizeME Touch.

V. OPPORTUNITY TO RESPOND TO THIS CITATION

13. Health and Med may respond to this Citation within 30 calendar days from the release date of this Citation by any of the following methods: (1) a written statement, (2) a teleconference interview, or (3) a personal interview at the Commission Field Office nearest to Company's place of business. The Commission Field Office nearest Health and Med is located in Los Angeles, California.

²⁹ 47 CFR § 2.803(b).

²⁶ Response to Supplemental LOI at 2, response to Inquiry 2.

²⁷ See, e.g., Health and Med, *IonizeMe Maxx 5*, <u>https://healthandmed.com/collections/1-user-ionic-detox-systems/products/ionizeme-maxx-5-the-most-powerful-ionic-detox-foot-bath-system</u> (last visited March 4, 2022).

²⁸ 47 U.S.C. § 302a(b).

³⁰ See Response to LOI at 3-4, Response to Question 12; Email from Mark Axelson, HealthandMed.com, to Jane Kelly, Attorney, Spectrum Enforcement Division, FCC Enforcement Bureau (Aug. 27, 2020) (on file in EB-SED-19-00029853) (Email and test results).

³¹ See Response to LOI at 4 and Excel spreadsheet attachment; see also supra para 7.

³² 47 U.S.C. § 302a(b); 47 CFR § 2.803(b).

14. If Company requests a teleconference or personal interview, contact Jane Kelly at jane.kelly@fcc.gov and EB-SED-Response@fcc.gov. We note that such teleconference or interview must take place within 30 calendar days of the release date of this Citation. If Health and Med prefers to submit a written response with supporting documentation, it must send the response within 30 calendar days of the contact provided in paragraph below.

15. All written communications should be sent via e-mail to jane.kelly@fcc.gov and to EB-SED Response@fcc.gov, and the subject line of the e-mail should specify the Company name and its investigation File Number, EB-SED-19-00029853. Due to network file size restrictions, the Company should partition the response into separate e-mails of less than 10 MB, including attachments. The Company should seek guidance in sufficient advance of the response deadline if it requires an alternative method of delivery.

16. Upon request, the Commission will make reasonable accommodations for persons with disabilities. If applicable, Health and Med should provide a description of the accommodation required, and include as much detail as possible, and also provide a telephone number and other contact information. Health and Med should allow at least five business days advance notice; last minute requests will be accepted but may be impossible to fill. Health and Med should send an e-mail to fcc504@fcc.gov or call the FCC's Consumer & Governmental Affairs Bureau:

For sign language interpreters, CART, and other reasonable accommodations:

202-418-0530 (voice), 202-418-0432 (tty);

For accessible format materials (braille, large print, electronic files, and audio format): 202-418-0531 (voice), 202-418-7365 (tty).

17. We advise Company that it is a violation of section 1.17 of the Commission's rules for any person to make any false or misleading written or oral statement of fact to the Commission.³³ Specifically, no person shall:

(1) In any written or oral statement of fact, intentionally provide material factual information that is incorrect or intentionally omit material information that is necessary to prevent any material factual statement that is made from being incorrect or misleading; and

(2) In any written statement of fact, provide material factual information that is incorrect or omit material information that is necessary to prevent any material factual statement that is made from being incorrect or misleading without a reasonable basis for believing that any such material factual statement is correct and not misleading.

18. Further, the knowing and willful making of any false statement, or the concealment of any material fact, in reply to this Citation is punishable by fine or imprisonment.³⁴

19. Violations of section 1.17 of the Commission's rules or the criminal statute referenced above may result in further legal action, including monetary forfeitures pursuant to section 503 of the Act.

20. Finally, we warn Company that, under the Privacy Act of 1974,³⁵ Commission staff will use all relevant material information before it, including information disclosed in interviews or written

³³ 47 CFR § 1.17.

³⁴ 18 U.S.C. § 1001.

³⁵ 5 U.S.C. § 552a(e)(3).

statements, to determine what, if any, enforcement action is required to ensure Health and Med's compliance with the Act and the Commission's rules.³⁶

VI. FUTURE VIOLATIONS

21. If, after receipt of this Citation, Health and Med again violates section 302 of the Act and/or section 2.803, and parts 2, 15, and/or 18 of the Commission's rules by engaging in conduct of the type described herein, the Commission may impose sanctions for each such violation. For example, the Commission may impose monetary forfeitures not to exceed \$22,021 for each such violation or each day of a continuing violation, and up to \$165,159 for any single act or failure to act.³⁷ The Commission may further adjust the forfeiture reflecting enumerated statutory factors, which include the nature, circumstances, extent, and gravity of the violation, and with respect to the violator, the degree of culpability, any history of prior offenses, ability to pay, and other such matters as justice may require.³⁸ Further, as discussed above, the Commission may assess forfeitures on both the conduct that led to this Citation and the conduct following it.³⁹

VII. ORDERING CLAUSES

22. Accordingly, **IT IS ORDERED** that, pursuant to sections 4(i) and 4(j) of the Act,⁴⁰ Health and Med must cease and desist from marketing unauthorized radio frequency equipment, in violation of section 302 of the Act and section 2.803 of the Commission's rules.⁴¹

23. **IT IS FURTHER ORDERED** that, pursuant to sections 4(i), 4(j), and 403 of the Act,⁴² Health and Med must provide the written information requested in paragraph 12 above. Health and Med must support its responses with an affidavit or declaration under penalty of perjury, signed and dated by an authorized officer of Health and Med with personal knowledge of the representations provided in the response, verifying the truth and accuracy of the information therein and that all of the information requested has been produced. All such declarations provided must comply with section 1.16 of the Commission's rules and be substantially in the form set forth therein.⁴³ The FCC must receive the response within 30 calendar days of the release date of this Citation and Order.

³⁸ See 47 U.S.C. § 503(b)(2)(E); 47 CFR § 1.80(b)(8).

³⁶ Any entity that is a "Small Business Concern" as defined in the Small Business Act (Pub. L. 85-536, as amended) may avail itself of rights set forth in that Act, including rights set forth in 15 U.S.C. § 657, "Oversight of Regulatory Enforcement," in addition to other rights set forth herein.

³⁷ See 47 U.S.C. § 503; 47 CFR § 1.80(b). These amounts are subject to further adjustment for inflation. See 47 CFR § 1.80(b)(9).

³⁹ See supra paragraph 1.

^{40 47} U.S.C. § 154(i), (j).

^{41 47} U.S.C. § 302; 47 CFR § 2.803(a)-(c).

⁴² 47 U.S.C. §§ 154(i),(j), 403.

⁴³ 47 CFR § 1.16.

24. **IT IS FURTHER ORDERED** that a copy of this Citation and Order shall be sent by email and by first class mail and certified mail, return receipt requested, to Mr. Mark Axelson, CEO, Health and Medical Sales, Inc. dba HealthandMed.com, 788 North 2150 W, Cedar City, Utah 84721-8487.

FEDERAL COMMUNICATIONS COMMISSION

Elizabeth Y. Mumaw Chief Spectrum Enforcement Division Enforcement Bureau

APPENDIX

Devices Marketed by HealthandMed.com-Dates of Marketing and Compliance⁴⁴

	SKU	Model	Date of First Sale	Date Ceased Marketing per Sales Report attached to follow up LOI	Date of Compliance with FCC labeling and user information disclosure rules
1	FBTOUCH-E- HW	IonizeMe Touch – Ionic Detox Foot Bath System with Hydrogen Drinking Water Option	Not provided	Still marketing as of February 10, 2022.	Evidence of authorization requested in this Citation.
2	FBMAXX- all variants	IonizeMe Maxx Ionic Detox Foot Bath System	3-2018	Still marketing as of February 10, 2022.	8-9-2019 for earlier variations.Evidence of authorization for IonizeMe Maxx 5 requested in this Citation.
3	FB 502	IonizeME basic	Before 1- 1-2018	Ceased marketing 2-2018	No evidence of authorization
4	FB622B-E	Ionic Detox Footbath System	Before 1- 1-2018	Ceased marketing 3-2018	No evidence of authorization
5	FBIMUL	IonizeME Ultra	Before 1- 1-2018	Ceased marketing 11-2018	No evidence of authorization
6	FB802-Е	IonizeME Premium Dual	Before 1- 1-2018	Ceased marketing 7-2018	No evidence of authorization
7	FBEDPLUS- all variants	IonizeME Elite Dual	Before 1- 1-2018	Ceased marketing 2-2019	No evidence of authorization
8	FBELITE- all variants	IonizeME Elite Ionic Detox	Before 1- 1-2018	Discontinued 4- 2020 to avoid testing costs	No evidence of authorization
9	FBMAXXD-E	IonizeME Maxx Dual	4-2018	Not on website as of February 10, 2022	Passed Part 15(B) testing 8-14-2020

⁴⁴ Attachment to Response to Letter of Inquiry from HealthandMed.com to FCC Enforcement Bureau (Feb. 14, 2020) (on file in EB-SED-00029853) and Response to Supplemental LOI and Attachments (June 3, 2020) (on file in EB-SED-19-19-00029853), Email from Mark Axelson to Jane Kelly, Spectrum Enforcement Division, (August 26, 2020) (on file in EB-SED-00029853), Email from Mark Axelson to Jane Kelly, Spectrum Enforcement Division, (August 27, 2020) (on file in EB-SED-00029853).

10	FBMAXXGO	IonizeME Maxx Go	11-2019	Still marketing as of February 10, 2022.	Passed Part 15(B) testing 8-13-2020
11	FB632- all variants	IonizeME Deluxe	Before 1- 1-2018	Not on website as of February 10, 2022.	No evidence of authorization
12	FB401-all variants	IonizeME Classic	Before 10-10- 2018	Not on website as of February 10, 2022.	No evidence of authorization
13	FB803- all variants	IonizeME Dual	Before 1- 1-2018	Not on website as of February 10, 2022.	No evidence of authorization
14	FB804- all variants	IonizeME Deluxe Dual	Before 1- 1-2018	Not on website as of February 10, 2022.	No evidence of authorization
15	FB805- all variants	IonizeME Deluxe Dual Plus	Before 1- 1-2018	Not on website as of February 10, 2022.	No evidence of authorization