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[Submitted Electronically and Sent First Class Mail]

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
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Citizen Petition and Request for Immediate Public Health Advisory

Children's Exposure to Unnecessary Radiation in Schools

Pursuant to 21 C.F.R. §§ 10.20, 10.30 (Citizen Petitions) and further to our prior Petition (Docket FDA-2023-P-2115) and the Letter of Denial from the Director of the Office of Policy at the Center for Devices and Radiological Health dated September 14, 2024, (attached hereto as Appendix C), petitioners Americans for Responsible Technology, Environmental Health Trust, Grassroots Environmental Education, Wired Broadband Inc., Consumers for Safe Cell Phones, Manhattan Neighbors for Safe Technology, Keep Cell Antennas Away, SafeTech NC, Massachusetts for Safe Technology, California Brain Tumor Association, and additional petitioners listed in Appendix A hereof (collectively, Petitioners) hereby respectfully submit this Citizen Petition requesting that the Commissioner of the Food and Drug Administration (FDA) immediately issue, implement, and carry out a Public Health Advisory to all public and private schools in the United States regarding the potential exposure of children to unnecessary amounts of radiofrequency (RF) radiation in school classrooms. The requested action is consistent with, and required by, 21 USC Federal Food, Drug and

Cosmetic Act, Subchapter V, Part C Electronic Product Radiation Control, Section 360ii - Program of Control, regarding public exposure to non-ionizing radiation.

STATEMENT OF GROUNDS

Petitioners are health, educational and environmental non-profit organizations, teachers, students, and parents and grandparents of children in public and private schools concerned with the human health risks associated with near-constant exposure of children to excess or unnecessary levels of RF radiation.

THE ISSUE

It is widely accepted that children are uniquely vulnerable to environmental threats of all kinds,¹ including radiation in all its forms.² Their rapidly developing physiology, their immature detoxification and elimination systems, and their behavioral patterns magnify any risks that may be present. Over the past several decades, numerous state and federal safety standards have been developed and implemented in recognition of this unique demographic.³

More recently, there has been a sea change in our educational system. The deployment of wireless technology is now ubiquitous in America's school classrooms.⁴ The exposure from multiple wireless devices is nearly constant and has whole-body effects on a uniquely vulnerable population. Wireless routers and access points in particular, which can account for 90% or more of the radiation in a classroom,⁵ are factory set for maximum radiated power and operate all day long, emitting radiation throughout the classroom. Despite the existence of this potentially hazardous exposure, there are no requirements for any measurement, evaluation, or remediation of excessive or unnecessary levels of radiation, putting children at risk.

¹ "Understanding Exposures in Children's Environments | US EPA." US EPA, 11 July 2024, www.epa.gov/healthresearch/understanding-exposures-childrens-environments.

² Moon, Jin-Hwa. "Health Effects of Electromagnetic Fields on Children." *Clinical and Experimental Pediatrics*, vol. 63, no. 11, May 2020, pp. 422–28. <https://doi.org/10.3345/cep.2019.01494>.

³ *Inter alia*, <https://www.nysed.gov/student-support-services/school-health-laws-and-regulations>

⁴ "95 Percent of Public-School Classrooms Have Wi-Fi." *Government Technology*, 18 Dec. 2023

⁵ Radio Frequency Radiation Assessment Test, Linbrook School, Oakville, ON L6J 2L2, accessed at https://www.techsafeschools.org/_files/ugd/2cea04_2f026547f5fd4702a0b6fe09934a9eed.pdf

After all, school is a child's second home - a place where they spend up to eight hours every day, day after day, week after week, for up to twelve years. However, unlike an adult's work environment where the Occupational Safety and Health Administration has jurisdiction and responsibility for ensuring a safe workplace, schools lack a single authority with broad oversight, instead relying on a patchwork of local, state, and federal agencies to identify potential risks and recommend remedial action. In this case, since the FDA has identified itself as having the authority and responsibility to oversee the safety and performance of electronic devices,⁶ it falls to the FDA to protect this vulnerable population by complying with applicable federal laws which require the agency to take action.

THE DEVICES

Wireless routers and access points in schools are used to connect children with each other, with their teachers, with the internet, and with the programs they use for instruction and review. Tablets, laptop computers, printers, projectors, smartboards and other classroom devices all connect to each other through routers and wireless access points.

All commercial routers and access points are delivered from the manufacturer pre-set for maximum power. Reducing the radiation emitted by these devices requires a manual adjustment of the output level, which is accomplished by accessing the software controlling the device. Absent complaints about interference with other devices, or any requirement for testing or evaluation to determine exactly how much power is required for the proper operation of the equipment, most routers and access points remain in full power mode, emitting far greater radiation than is actually required for the accomplishment of the product's primary purpose.⁷

In denying our previous request for the FDA to comply with the law regarding Sections (a)(2), (a)(4) and (a)(5) of 21 USC 360ii, the agency claims it only has responsibility to protect the public from "unnecessary" radiation, which the agency defines in several ways, including

⁶ Center for Devices and Radiological Health. "Electronic Product Radiation Control Program." U.S. Food And Drug Administration, 23 Feb. 2023, www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program.

⁷ An analysis of RF radiation in the Linbrook School in Oakville, Ontario revealed that the radiation in classrooms could be reduced by as much as 90% while still retaining full functionality. See Appendix B.

"the minimal amount of radiation that is reasonably required for the accomplishment of a product's primary purpose."

The excess or unnecessary radiation emitted from a classroom router or access point operating as designed is not a "defect" as defined in 21 CFR 1003.2, and no such claim is made here. Manufacturers of these devices cannot remedy a situation in which the device emits more radiation than is required for the task at hand. The only remedy is for school administrators, IT staff, or other qualified personnel to manually adjust the amount of radiation emitted from the device so as not to create excessive and unnecessary radiation in the classroom.

Likewise, current human exposure standards for RF radiation should not be applied in this case. Back in the last century, the Federal Communications Commission developed and promoted public exposure standards for electronic devices emitting radiation to protect the public from the harm that was understood to result from excess or unnecessary exposure. These standards, based on adult models and developed long before the introduction of wireless technologies into school classrooms, bear no relationship to a child's exposure in school, and should not be used to excuse or justify the exposure of any child to any level of unnecessary radiation.

SPECIFIC ACTION REQUESTED

Congress has identified the risk from the public's exposure to electronic devices which emit radiation and passed legislation requiring the FDA to take action to protect the public.⁸ The FDA has acknowledged its obligation to act when there is evidence of unnecessary emissions of radiation.⁹

Petitioners therefore request that the FDA issue a Public Health Advisory to all public and private schools and day care centers in the United States, alerting them of the possibility

⁸ Specifically, 21 USC 360 ii Sections (a)(2), (a)(4) and (a)(5).

⁹ Letter from Ellen Flannery, Director of the Office of Policy at the Center for Devices and Radiological Health dated September 14, 2024, page 5: "This statutory directive ... requires the Agency to assess and determine the extent to which electronic product radiation from a particular product is unnecessary, and, to the extent it is unnecessary, the FDA takes action accordingly."

that radiation in excess of the amount required for the proper operation of wireless devices may be present in their facilities, and including instructions for mitigating such unnecessary exposures. Petitioners recommend that such advisories shall include language substantially similar to the following example:

**FDA Advises Schools to Reduce Radiation from
Wireless Routers and Access Points Due to Potential for Children's
Exposure to Unnecessary Radiofrequency Radiation**

FDA advises all school administrators and IT staff members to reduce the amount of radiation emitted from classroom routers and wireless access points to the lowest level required to maintain connectivity among wireless devices in the classroom. This level may be far below the factory-set power level established by the manufacturer.

Children are uniquely vulnerable and sensitive to all types of environmental exposures. Long-term exposure to excessive and unnecessary levels of radiofrequency (RF) radiation may result in both acute and chronic health impacts.

For specific information about how to test for and reduce exposure levels in classrooms, please download FDA's pamphlet "Information for Administrators and IT Staff on Reducing Radiation Exposures in Classrooms"¹⁰

¹⁰ This link would lead to an FDA document similar to this:
https://www.techsafeschools.org/_files/ugd/2cea04_a1dbbc4a18234fa599cdd02265e2337a.pdf

CONCLUSION

Children in America's schools are at risk from exposure to excessive and unnecessary levels of radiation emitted from routers and wireless access points. The law mandates that steps be taken to reduce the public's exposure to unnecessary radiation. FDA has identified unnecessary radiation as radiation in excess of that required for the operation of an electronic device. FDA has the authority and responsibility to take the action requested.

ENVIRONMENTAL IMPACT

Petitioners claim a categorical exclusion under one or more provisions of 21 C.F.R. §§ 25.30- 25.34.

CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition and its attachments includes all information and views on which the petition relies.



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Appendix B

Chart of Electronic Product Radiation Reduction in Typical Elementary School

EMR Technician: Bryan Fromm - Electronics Engineering Technician

Testing Date: Sunday February 7th, 2016

Arrival on-site: 9:00 AM

Testing Time: 9:10 AM – 11:00 AM

Location	Sunday September 27 th , 2015		Sunday February 7 th , 2016 Measurements in Center of Room		Sunday February 7 th , 2016 Measurements at Seat Closest to Router		Measurement Location: Center of Room		Measurement Location: Closest Seat to Router	
	HFE59B 27 MHz - 3.3 GHz μW/m ² (microwatts/ sq. meter) W/EI ON	HFEW59D 2.4 GHz - 10 GHz μW/m ² (microwatts/sq. meter) W/EI ON	HFE59B 27 MHz - 3.3 GHz μW/m ² (microwatts/ sq. meter) W/EI ON	HFEW59D 2.4 GHz - 10 GHz μW/m ² (microwatts/sq. meter) W/EI ON	HFE59B 27 MHz - 3.3 GHz μW/m ² (microwatts/ sq. meter) W/EI ON	HFEW59D 2.4 GHz - 10 GHz μW/m ² (microwatts/sq. meter) W/EI ON	HFE59B Percent Reduction	HFEW59D Percent Reduction	HFE59B Percent Reduction	HFEW59D Percent Reduction
Art Room	18,000	37,000	1100	2200	2800	4600	93.89%	94.05%	84.44%	87.57%
I.T Office	1100	15,000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
S.K Classroom	15,000	23,000	450	750	2200	2500	97.00%	96.74%	85.33%	89.13%
J.K Classroom	16,000	28,000	470	470	1800	2200	97.06%	98.32%	88.75%	92.14%
Grade 2 Classroom	17,000	22,000	530	800	1600	950	96.88%	96.36%	90.59%	95.68%
Grade 1 Classroom	26,000	50,000	600	800	1700	1850	97.69%	98.40%	93.46%	96.30%
Gymnasium	9000	9700	175	121	470	430	98.06%	98.75%	94.78%	95.57%
Grade 3 Classroom	27,000	30,000	1270	1550	2500	2650	95.30%	94.83%	90.74%	91.17%
Office Room 118 - Amber	2000	5000	78	20	N/A	N/A	96.10%	99.60%	N/A	N/A
Office Room 119 - Mike	31,000	33,000	5000	4300	N/A	N/A	83.87%	86.97%	N/A	N/A
Grade 4 Classroom	19,000	19,000	4300	2700	2300	1700	77.37%	85.79%	87.89%	91.05%
Grade 5 Classroom	17,000	23,000	440	600	3100	3100	97.41%	97.39%	81.76%	86.52%
Grade 6 Classroom	18,000	33,000	370	580	1000	1400	97.94%	98.24%	94.44%	95.76%
Grade 7 Classroom	15,000	22,000	500	350	780	1000	96.67%	98.41%	94.80%	95.45%
Grade 8 Classroom	32,000	37,000	500	1440	1360	1800	98.44%	96.11%	95.75%	95.14%
Library	2700	6000	1440	1590	1440	1590	46.67%	73.50%	46.67%	73.50%
Outside - near Park	650	130	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Music Room	70	150	189	73	N/A	N/A	-	170.00%	51.33%	N/A
Gymnasium(On Stage)	1800	1500	20	77	20	77	98.89%	94.87%	98.89%	94.89%

The full report from Safe Living Technologies can be accessed at
https://www.techsafeschools.org/files/ugd/2cea04_2f026547f5fd4702a0b6fe09934a9eed.pdf



September 14, 2024

Douglas A. Wood
Americans for Responsible Technology
184 Main Street
Port Washington, NY

Sent via email to: daw@grassrootsinfo.org

Re: Citizen Petition – Docket Number FDA-2023-P-2115

Dear Mr. Wood:

This letter responds to your citizen petition received on May 24, 2023, requesting the Food and Drug Administration (FDA) take certain actions to satisfy administrative obligations under section 532(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding public exposure to non-ionizing radiation, particularly as they relate to non-medical products and devices emitting such non-ionizing radiation. FDA provided an interim response to your petition on November 12, 2023. We have carefully reviewed the materials and arguments set forth in your citizen petition and, for the reasons outlined below, we deny the petition under 21 CFR 10.30(e)(3).

I. Action Requested

In your petition, you request the FDA Commissioner take the following actions as they relate to non-medical products and devices emitting non-ionizing radiation:

- (i) direct the Center for Devices and Radiological Health (CDRH) or other division of FDA to take actions as may be required to bring FDA into compliance with 21 U.S.C. 360ii(a)(2) [section 532(a)(2) of the FD&C Act]
- (ii) direct CDRH or other division of FDA to take actions as may be required to bring FDA into compliance with 21 U.S.C. 360ii(a)(4) [section 532(a)(4) of the FD&C Act]
- (iii) direct CDRH or other division of FDA to take actions as may be required to bring FDA into compliance with 21 U.S.C. 360ii(a)(5) [section 532(a)(5) of the FD&C Act]

You also identify various hypothetical actions that FDA could take in accordance with the directives outlined in section 532(a) of the FD&C Act, and request that FDA “produce and make public information detailing its activities and administrative actions that demonstrate full compliance with the specifications of the statute...”¹

¹ Petition, pp. 4-5.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov



II. Legal Background

FDA is responsible for regulating radiation-emitting electronic products through the Radiation Control provisions of the FD&C Act (originally enacted as the Radiation Control for Health and Safety Act of 1968), which are in sections 531 through 542 of the FD&C Act (“Radiation Control” or “EPRC” provisions). The Radiation Control provisions apply to any “electronic product,” which is defined as: “(A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation” (section 531(2) of the FD&C Act; see also 21 CFR 1000.3(j)).

Under the Radiation Control provisions, FDA has established and carries out an electronic product radiation control (EPRC) program designed to protect the public health and safety from electronic product radiation (see section 532 of the FD&C Act). Pursuant to the program, FDA regulates the manufacturers of radiation emitting electronic products, including both electromagnetic (ionizing and non-ionizing) and sonic radiation.² As part of the program, FDA, among other things, must conduct certain activities related to electronic products to “minimize the emissions of and the exposure of people to, unnecessary electronic product radiation” (section 532(a)(2) of the FD&C Act). These activities include “plan[ing], conduct[ing], coordinat[ing], and support[ing] research, development, training, and [other] operational activities” (*id.*). Also as part of the program, FDA must “study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields” (section 532(a)(4) of the FD&C Act) and “develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation” (section 532(a)(5) of the FD&C Act).

Separately, if FDA determines that emissions of and exposure to unnecessary electronic product radiation need to be controlled for the protection of the public health and safety, sections 534 and 535 of the FD&C Act describe the Agency’s obligation to do so through development of performance standards and notification to manufacturers of failures to comply or product defects, respectively.

III. Discussion

In accordance with 21 CFR 10.25, an interested person may submit a citizen petition to FDA requesting that the Agency “issue, amend, or revoke a regulation or order” or “take or refrain from taking any other form of administrative action.” A petition requesting FDA to take

² Section 531 of the FD&C Act defines the term “electronic product radiation” to mean “(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.”



or refrain from taking any form of administrative action under 21 CFR 10.30 must be in accordance with certain format requirements, among other things, including specifying “the specific action or relief requested” (see § 10.30(b)(3)). Your citizen petition, however, does not specify any specific action or relief you are requesting.

Your petition requests that FDA “direct [CDRH] or other division of FDA to take actions as may be required to bring FDA into compliance with” certain Radiation Control provisions, and provides various hypothetical examples of how these statutory requirements “might be satisfied.”³ For example, in requesting FDA to “plan, conduct, coordinate, and/or support research, development, training, and operational activities to minimize” unnecessary electronic product radiation exposure as described in section 532(a)(2) of the FD&C Act, your petition includes a variety of optional activities, which “might [include]... coordinating or conducting professional training of medical, educational, and commercial providers,” “could include participation at continuing medical education conferences,” or “FDA could develop its own exposure reduction techniques.”⁴ These actions, among other hypothetical actions articulated in the petition, are not specific actions requested as required by 21 CFR 10.30(b)(3), but rather a range of general suggestions put forth for consideration.

Additionally, with respect to your request that FDA “study and evaluate emissions of, and conditions of exposure to, electronic product radiation” as described in section 532(a)(4) of the FD&C Act, you provide examples of radiation exposure in various environments, such as schools, and claim that “FDA is failing to monitor these exposures” based on an asserted absence of information on FDA’s website.⁵ Your petition requests FDA “to take such actions as may be required to bring FDA into full compliance with [section 532(a)(4)],” including “specifically to study and evaluate the conditions of the public’s many sources of exposure to non-ionizing radiation, including the impact of peak exposures and chronic exposures of children occurring in schools, and to produce and make public regularly updated information detailing the agency’s actions to help the public reduce its exposures.”⁶ This is not a request for a specific administrative action as required under 21 CFR 10.30(b)(3), but a request that FDA “carry[] out the requirements of [the Radiation Control provisions]” more generally, with examples of certain activities more specifically.⁷

Moreover, in requesting FDA to engage with stakeholders to “[d]evelop [p]rocedures and [t]echniques for [m]inimizing [e]xposure” as described in section 532(a)(5) of the FD&C Act, your petition provides a variety of examples of what this engagement could look like and what these new procedures could be.⁸ For example, “[s]uch procedures might include working with wireless device manufacturers to provide a one-button disconnect that would immediately

³ Petition, p. 8.

⁴ Petition, pp. 6-8.

⁵ Petition, p. 11.

⁶ Petition, p. 13.

⁷ *Id.*

⁸ Petition, p 13.



disable all wireless antennas,” “new cars could be outfitted with a switch to turn off all unnecessary wireless circuits,” “routers could be manufactured with circuits to automatically turn off when not in use,” “public buildings could provide radiation-free zones,” “[c]olleges and universities could be encouraged to set aside spaces where non-ionizing radiation is minimized,” “[h]otels could be encouraged to provide ‘Wi-Fi-free’ rooms,” “wireless devices could be required to include more prominent consumer warnings,” and “FDA could engage with companies that provide shielding materials to reduce the transmission of radiation through walls and windows...”⁹ Similarly, these actions, among other hypothetical actions articulated in the petition, are not specific actions requested as required by 21 CFR 10.30(b)(3), but rather a range of general suggestions put forth for consideration.

Likewise, “if the petition requests the Commissioner to issue, amend, or revoke a regulation” under 21 CFR 10.30, it must also be in accordance with certain format requirements, among other things, including providing “the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested” (see § 10.30(b)(3)). While it is possible that you are asking FDA to issue a type of proposed rule (e.g., your citizen petition states that “requiring commercial providers to participate in the development of exposure reduction techniques, such as one-button wireless disconnects, which could then be promulgated by FDA”), your petition does not request any particular rule or provide any wording or other details of a proposed regulation, as required by 21 CFR 10.30(b)(3).

Even assuming your petition met the required elements discussed above, at this time, FDA is declining to use the Agency’s resources in this way. This is taking into account the broad scope and overall workload of the Agency and its priorities, as well as the numerous ongoing activities FDA is conducting as required by the Radiation Control provisions. 21 CFR 10.30(e)(1) provides that the Commissioner rule upon each petition “taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.” At this time, and for the reasons discussed below, we decline to use our resources to conduct the various hypothetical activities requested.

Furthermore, your petition is premised on your assertion that FDA is not in compliance with certain Radiation Control Provisions. In support, you give various examples of what you assert to be FDA’s failure to undertake certain actions.¹⁰ FDA disagrees with the premise of

⁹ Petition, pp. 13-14.

¹⁰ Section 5 of your petition includes information that is separate from the sections in which you articulate the three actions requested, and does not explain how this information is connected to your requested actions. Instead, the information appears to provide various examples of FDA’s alleged failures to undertake certain actions as part of the EPRC program. For example, your petition states “[t]eachers, many of whom are of child-bearing age, are being exposed throughout the day to the cumulative non-ionizing radiation emanating from all wireless devices in the classroom. Some studies have shown that exposure during pregnancy can disrupt normal brain development [citing Aldad, et al, Fetal Radiofrequency Radiation Exposure From 800-1900 Mhz-Rated Cellular Telephones Affects



your requests because the Agency is in compliance with the Radiation Control Provisions, as described more fully below.

a. FDA is Undertaking the Necessary Activities to Minimize Unnecessary Electronic Product Radiation.

Your first request is that FDA “take such actions as may be required to bring FDA into full compliance with § 360ii(a)(2) [(section 532(a)(2) of the FD&C Act)], including regularly producing and making public information detailing the agency’s actions that help consumers reduce their exposures.”¹¹

Section 532(a)(2) of the FD&C Act requires the Secretary to “plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to unnecessary electronic product radiation.” This statutory directive takes into account the regulatory approach of balancing benefits and risks, as it requires the Agency to assess and determine the extent to which electronic radiation from a particular product is unnecessary and, to the extent it is unnecessary, FDA takes action accordingly.

For example, in accordance with section 535 of the FD&C Act, the Agency assesses and determines the extent to which electronic products fail to comply with applicable standards or contain defects. An electronic product is considered to have a defect relating to the safety of its use by reason of the emission of electronic product radiation if “[i]t is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, ... [but] emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person.”¹² Essentially, the minimal amount of radiation that is reasonably required for the accomplishment of a product’s primary purpose may be considered necessary; whereas, levels of radiation beyond this minimum and/or radiation that creates an unreasonable risk of harm may be considered unnecessary. FDA undertakes research and engages with stakeholders to better understand, for products and product types, what radiation is unnecessary to the accomplishment of their primary purpose and/or where they otherwise pose a risk to human health that should be addressed in order to protect the public health and safety (see Section III.b. below). As appropriate, FDA will produce and make public information detailing its activities, administrative actions, and actions that consumers can take to reduce exposure. To illustrate with a specific example, in 2022 (and

Neurodevelopment and Behavior in Mice, *Sci Rep.* 2012; 2: 312] ... nevertheless, the FDA is ... [not] carrying out the activities prescribed by law that could provide teachers and administrators with information to help them reduce exposures in classrooms” (Petition, p. 19). In light of the various information provided (including with respect to your expressed concerns regarding pregnant teachers in classrooms) the information’s relevance to each of the actions requested is difficult to ascertain and evaluate because it does not identify how it relates to any specific action requested. As such, for the reasons discussed herein detailing FDA’s existing compliance with the Radiation Control provisions under section 532(a), FDA will not opine on the potential relevance or adequacy of that information.

¹¹ Petition, p. 9.

¹² 21 CFR 1003.2(b)(2).



updated in 2023), FDA issued a Safety Communication to warn consumers about the potential risk of injury associated with the use of certain brands of ultraviolet (UV) wands.¹³ This communication followed FDA activities to plan, conduct, and coordinate on activities to collect and test samples of UV wands from multiple manufacturers and issuance of Notification of Defect Letters to UV wand manufacturers whose products were found to give off unsafe levels of radiation that posed a significant risk of injury to consumers.

The Radiation Control provisions require FDA to engage in training and operational activities that result in minimizing the public’s “unnecessary” exposure to electronic product radiation. The Radiation Control provisions do not require the EPRC program to concentrate on specific electronic product types, undertake specific development, training, and operational activities, or prescribe specific performance standards.¹⁴ As such, under FDA’s obligation to minimize the emissions of and exposure of people to unnecessary electronic product radiation, and taking into account the resources available to the Agency, FDA generally focuses its time and resources on product types that are believed to present greater risk to public health. FDA undertakes the necessary activities to plan, conduct, coordinate, and support research, development, training, and operational activities to identify new risks and inform FDA’s determination of whether development of performance standards or other regulatory options or other actions may be appropriate to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation.

1. Research

FDA conducts ongoing assessments across various product types to identify areas for

¹³ FDA, Do Not Use Ultraviolet (UV) Wands That Give Off Unsafe Levels of Radiation: FDA Safety Communication, available at <https://www.fda.gov/medical-devices/safety-communications/do-not-use-ultraviolet-uv-wands-give-unsafe-levels-radiation-fda-safety-communication>.

¹⁴ For purposes of the Radiation Control provisions, electronic product radiation is defined to include both ionizing and non-ionizing radiation. Section 531(1) of the FD&C Act.

research and prioritize its regulatory activities.^{15,16,17,18,19, 20,21,22} In conducting, coordinating, and planning research activities, FDA considers the regulatory needs for both products and product types known to present risk and those where new information warrants research to better understand the risk. For example, FDA may purchase and test product samples to better understand the risks of these products, taking into consideration information from external stakeholders and accidental radiation occurrence reports to determine research needs.²³

2. Development of Policies and Regulations

Furthermore, FDA may take the lead to develop new policies and regulations to minimize emissions of and exposure of people to unnecessary electronic product radiation, as well as planning of strategies to address associated public health risks. For example, for products with performance standards, FDA may work to develop procedures and reference materials to ensure manufacturers and inspectors can successfully evaluate product adherence to such standards.²⁴

As noted in the prior section, FDA conducts ongoing assessments across various product types to identify areas for research and prioritize its regulatory activities. FDA also disseminates public information through research articles, guidance, and other public-facing communications. FDA has issued a number of guidance documents illustrating FDA's approach to manufacturer compliance with performance standards and other aspects of the EPRC provisions and implementing regulations. For example, these guidance documents cover performance standards

¹⁵ See, e.g., Spelic, David & Hilohi, Mike & Farris, Karen & Eicholtz, George & Elee, Jennifer & Ortego, Josephine & Kaus, Gary. (2016). The Nationwide Evaluation of X-Ray Trends, Part I: More Than 40 Years of Surveying the US Radiology Practice. *Journal of the American College of Radiology*. 13. 713-715. 10.1016/j.jacr.2016.03.013.

¹⁶ See, e.g., Delfino JG, Krainak DM, Flesher SA, Miller DL. A 10-year Review of MRI-Related FDA Adverse Event Reports. ISMRM/SMRT 28th Annual Meeting (virtual conference and exhibition). August 2020.

¹⁷ See, e.g., FDA, Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer, February 2020, available at <https://www.fda.gov/media/135043/download>.

¹⁸ See, e.g., Wear, Keith. (2020). Hydrophone Spatial Averaging Correction for Acoustic Exposure Measurements from Arrays I: Theory and Impact on Diagnostic Safety Indexes. *IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control*. PP. 1-1. 10.1109/TUFFC.2020.3037946.

¹⁹ See, e.g., Strzelecki, Wlodzimierz & James, Robert & Ilev, I. (2017). Quantitative Evaluation of a Time-Dependent Eye Hazard Posed by Laser Pointers. *Health physics*. 113. 375-381. 10.1097/HP.0000000000000714.

²⁰ See, e.g., Milder CM, Borrego D, Preston DL, Villoing D, Kwon T, Miller DL, Alexander BH, Linet MS, Lee C, Kitahara CM. Occupational radiation dose trends in U.S. radiologic technologists assisting with fluoroscopically-guided interventional procedures, 1980-2020. *J Vasc Interv Radiol* 2024; 35(7):1057-1065.e4. doi: 10.1016/j.jvir.2024.03.032 epub 2024 Apr 08.

²¹ See, e.g., Moradi, Mousa & Vasudevan, Sandhya & Bhusal, Anant & Weininger, Sandy & Chen, Yu & Pfefer, Joshua. (2024). Modeling light-tissue interactions in pulse oximetry: effect of device design and skin pigmentation. 10.1117/12.3004189.

²² See, e.g., Inter-laboratory Evaluation of Ultraviolet Radiation Emissions from Compact Fluorescent Lamps. January 2016. *Photochemistry and Photobiology* 92(2). 92(2) DOI:[10.1111/php.12573](https://doi.org/10.1111/php.12573)

²³ See 21 CFR 1003.11(a); Compliance Testing of Radiation Emitting Electronic Products at Winchester Engineering & Analytical Center (WEAC). FDA CPMG 7386.006, available at <https://www.fda.gov/media/165615/download>.

²⁴ Inspection and Field Testing of Radiation-Emitting Electronic Products. FDA CPMG 7386.001, available at <https://www.fda.gov/media/74525/download>.

for devices and radiation-emitting products including, but not limited to, diagnostic x-ray systems, laser products, and high-intensity mercury vapor discharge lamps.^{25,26,27,28} FDA also maintains webpages dedicated to the EPRC program²⁹ and maintains a distribution list for broad communications based on areas of interest.³⁰

In accordance with FDA’s administration of the EPRC program, FDA prescribes and amends performance standards for electronic products to control the emissions of electronic product radiation when necessary to protect the public health and safety.^{31,32} FDA coordinates and enforces regulatory requirements, including enforcement of regulations regarding records and reports,³³ import controls,³⁴ and notification of defects or failure to comply.³⁵

3. Training

In addition, FDA coordinates the efforts around training for FDA staff and external stakeholders, including formal training, external presentations, guidance and other communications. For example, FDA’s Compliance Program Guidance Manual (CPGM) provides instruction to FDA personnel for conducting activities related to evaluating a manufacturer’s compliance with the EPRC provisions and implementing regulations.³⁶ FDA trains ORA personnel who conduct inspections, import sampling and laboratory testing of

²⁵ See, e.g., Guidance for Industry and FDA Staff - Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21 CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/performance-standard-diagnostic-x-ray-systems-and-their-major-components-21-cfr-102030-102031-102032>.

²⁶ See, e.g., Laser Products – Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56) - Guidance for Industry and Food and Drug Administration, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56>.

²⁷ See, e.g., Guidance for Industry and FDA Staff: Applicability of the Performance Standard for High-Intensity Mercury Vapor Discharge Lamps (21 CFR 1040.30), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applicability-performance-standard-high-intensity-mercury-vapor-discharge-lamps-21-cfr-104030>.

²⁸ Additional guidance documents can be located on FDA’s website, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, by selecting “Radiation-Emitting Products” in the “Product” drop-down menu.

²⁹ FDA, Electronic Product Radiation Control Program, available at <https://www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program>.

³⁰ Subscribe to CDRH Email Lists, available at <https://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-email-lists>.

³¹ See 21 CFR parts 1010-1040.

³² See, e.g., Sunlamp Products; Proposed Amendment to Performance Standard, available at <https://www.federalregister.gov/documents/2015/12/22/2015-32023/sunlamp-products-proposed-amendment-to-performance-standard>.

³³ See 21 CFR part 1002.

³⁴ See 21 CFR part 1005.

³⁵ See 21 CFR 1003, subpart C.

³⁶ FDA, Compliance Program Manual, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-manual>.

radiation emitting products based on the CPGM. As noted in the prior section, FDA provides instruction and guidance to industry and the public in the form of guidance documents detailing FDA’s approach regarding compliance with performance standards and other aspects of the EPRC provisions and implementing regulations, as well as FDA webpages dedicated to the EPRC program. FDA participates in conferences to further educate the public, healthcare providers, and industry.^{37,38,39}

4. Operational Activities

Finally, FDA conducts a broad array of operational activities to administer the EPRC program, including, but not limited to, information collection, recordkeeping, budget planning, and communications. For example, FDA recently issued a final rule to amend aspects of the EPRC records and reporting requirements.⁴⁰ Besides conducting necessary internal operational activities, FDA funds external organizations to support radiation protection.^{41,42} FDA makes information on compliance operations publicly available, as appropriate. For example, FDA publishes a list of firms and their products subject to import detention for failure to comply with performance standards or to have required certification.⁴³ FDA publishes communications to notify the public of the benefits and risks of certain products, and actions that manufacturers, healthcare providers, and consumers can take to reduce exposure.^{44,45,46,47,48}

FDA activities in compliance with the Radiation Control provisions are further detailed in

³⁷ See, e.g., Regulatory Education for Industry (REdi) 2023 Conference Day 4 – Radiation-Emitting Medical Devices Update, available at <https://sbiaevents.com/files2023/REdi-2023-Agenda.pdf>.

³⁸ See, e.g., “Radiation Management in Pregnancy—Patients and Staff”, Society of Interventional Radiology, 2017 SIR Annual Scientific Meeting, Washington, DC, Workshop: Protection for Patients and Staff, March 6, 2017.

³⁹ See, e.g., Delfino JG, Krainak DM, Flesher SA, Miller DL. A 10-year Review of MRI-Related FDA Adverse Event Reports. ISMRM/SMRT 28th Annual Meeting (virtual conference and exhibition). August 2020, available at <https://archive.ismrm.org/2020/1119.html>.

⁴⁰ Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products (88 FR 3638), available at <https://www.federalregister.gov/documents/2023/01/20/2023-00922/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic>.

⁴¹ See, e.g., Funding Opportunity: Assuring Radiation Protection: RFA-FD-18-021: Assuring Radiation Protection (U18), available at <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-18-021.html>.

⁴² See, e.g., Image Gently and Digital Radiography - Quality Improvement, available at <https://www.imagegently.org/Procedures/Digital-Radiography/Quality-Improvement>.

⁴³ See, e.g., Import Alert 95-05, available at: https://www.accessdata.fda.gov/cms_ia/importalert_255.html.

⁴⁴ See, e.g., Minimizing Risk for Children’s Toy Laser Products, available at <https://www.fda.gov/media/86481/download>.

⁴⁵ See, e.g., Ultrasound Imaging, available at: <https://www.fda.gov/radiation-emitting-products/medical-imaging/ultrasound-imaging>.

⁴⁶ See, e.g., Reducing Radio Frequency Exposure from Cell Phones, available at: <https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure-cell-phones>

⁴⁷ See, e.g., Microwave Ovens, available at: <https://www.fda.gov/radiation-emitting-products/resources-you-radiation-emitting-products/microwave-ovens>.

⁴⁸ See, e.g., Sunlamps and Sunlamp Products (Tanning Beds/Booths), available at: <https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/sunlamps-and-sunlamp-products-tanning-bedsbooths>.



the sections below.

b. FDA is Conducting the Necessary Activities to Study and Evaluate Emissions of, and Conditions of Exposure to, Electronic Product Radiation and Intense Magnetic Fields.

Your second request is that FDA “take such actions as may be required to bring FDA into full compliance with the law, and specifically to study and evaluate the conditions of the public’s many sources of exposure to non-ionizing radiation, including the impact of peak exposures and chronic exposures of children occurring in schools, and to produce and make public regularly updated information detailing the agency’s actions to help the public reduce its exposures.”⁴⁹ Your petition references various types of electronic products, such as “routers, smart utility meters, cordless phones, GPS devices, wireless computer keyboards, tablets, virtual reality headsets, baby monitors, [and] wearables,” as the types of products that FDA is required to study in accordance with section 532(a)(4) of the FD&C Act.⁵⁰

Section 532(a)(4) of the FD&C Act requires the Secretary to “study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields.” FDA has been studying and evaluating emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields, including with respect to non-ionizing and non-medical radiation emitting products. As noted above, FDA generally focuses on product types that are believed to present greater risk to public health, but continues to monitor all radiation emitting electronic products to identify new risks and inform FDA’s determination of whether development of performance standards or other regulatory options or other actions may be appropriate. FDA activities in compliance with the Radiation Control provisions are detailed further below.

1. Research

The range of electronic products on the market is diverse with varying levels of radiation emission, product complexity, consumer use, and sales volume. The public risk associated with exposure to radiation from these products also varies greatly. As previously noted, FDA conducts an ongoing assessment across the various product types to identify areas for research and prioritize its research activities. FDA considers the regulatory need for both high-risk products and product types where new information warrants research to better understand the risks or potential mitigations. Once an area warranting research has been identified, FDA may determine whether to conduct the research within the Agency or in coordination with external organizations. For example, FDA’s Winchester Engineering and Analytical Center (WEAC) has the capability to study and evaluate the safety and compliance of certain radiation-emitting

⁴⁹ Petition, p. 13.

⁵⁰ Petition, p. 10.



electronic products.⁵¹

FDA staff conduct research on electromagnetic and electrical safety.⁵² FDA staff independently, or in collaboration with stakeholders, engage on projects across a spectrum of radiation emitting electronic product types to develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation. Experts within FDA monitor and review the body of relevant data, including the latest available scientific and medical data in the field of electronic product radiation to evaluate the conditions of exposure to electronic product radiation and intense magnetic fields that may present a risk to human health. This helps FDA determine if it should revise existing performance standards, develop additional performance standards, or take other actions. Independently, or in collaboration with stakeholders, research results are made public through presentations at national conferences and in publications.^{53,54,55,56,57,58,59}

2. Guidance and Stakeholder Interaction

FDA representatives engage with and answer questions from individual firms regarding radiation emitting electronic products.⁶⁰ FDA collaborates with industry and radiological professional organizations to evaluate and promote the safety of radiation emitting electronic

⁵¹ Compliance Testing of Radiation Emitting Electronic Products at Winchester Engineering & Analytical Center (WEAC). FDA CPMG 7386.006, available at <https://www.fda.gov/media/165615/download>.

⁵² [Electromagnetic and Electrical Safety Program: Research on the Electromagnetic and Electrical Safety of Medical Devices | FDA](#)

⁵³ See, e.g., National Council on Radiation Protection and Measurements. Medical Radiation Exposure of Patients in the United States. Report No. 184. Bethesda, MD: National Council on Radiation Protection and Measurements, 2019. (Member) Available at <https://ncrponline.org/shop/reports/report-no-184-medical-radiation-exposure-of-patients-in-the-united-states-2019/>.

⁵⁴ See, e.g., FDA, Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer, February 2020, available at <https://www.fda.gov/media/135043/download>.

⁵⁵ See, e.g., Mahmood U, et al., Survey of pediatric fluoroscopic air kerma rate values and recommended application of results. AAPM Report No. 251. Alexandria, VA: American Association of Physicists in Medicine, 2022, available at: https://www.aapm.org/pubs/reports/RPT_251.pdf.

⁵⁶ See, e.g., Bassen, Howard & Angelone, Leonardo. (2012). Evaluation of unintended electrical stimulation from MR gradient fields. *Frontiers in bioscience (Elite edition)*. 4. 1731-42. 10.2741/E494.

⁵⁷ See, e.g., Park, Bu & Guag, Joshua & Jeong, Hongbae & Rajan, Sunder & McCright, Brent. (2023). A new method to improve RF safety of implantable medical devices using inductive coupling at 3.0 T MRI. *Magma (New York, N.Y.)*. 36. 10.1007/s10334-023-01109-8.

⁵⁸ See, e.g., Wear, Keith & Vaezy, Shahram. (2020). Note to Physicians and Sonographers on Potential Underestimation of Acoustic Safety Indexes for Diagnostic Array Transducers. *IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control*. PP. 1-1. 10.1109/TUFFC.2020.3038000.

⁵⁹ See, e.g., Delfino, Jana & Woods, Terry. (2016). New Developments in Standards for MRI Safety Testing of Medical Devices. *Current Radiology Reports*. 4. 10.1007/s40134-016-0155-y.

⁶⁰ See, e.g., FDA, Getting a Radiation Emitting Product to Market: Frequently Asked Questions, available at <https://www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program/getting-radiation-emitting-product-market-frequently-asked-questions>.



products.^{61,62,63} FDA is a participant in the Interagency Steering Committee on Radiation Standards (ISCORS).⁶⁴ FDA is a board liaison to the Conference of Radiation Control Program Directors (CRCPD), and participates at its annual meeting and in multiple workgroups.⁶⁵ Multiple FDA staff serve as council members on the National Council on Radiation Protection & Measurements.⁶⁶ FDA is on the Commission of the International Commission on Non-Ionizing Radiation Protection.⁶⁷ FDA engages with other Federal Department and Agencies on other committees and activities.^{68,69,70} The collaborations stem from a common interest that FDA has with other stakeholders to study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields in order to reduce unnecessary exposure.

3. Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC)

The TEPRSSC provides advice to FDA in evaluating the technical feasibility, reasonableness, and practicality of all proposed performance standards for electronic products and may make recommendations on electronic product radiation safety standards and other matters appropriate in fulfilling the purposes of the Act.⁷¹ FDA must consult with TEPRSSC prior to prescribing any performance standard. Following FDA activities to study and evaluate emissions of, and conditions of exposure to, electronic product radiation and monitoring radiation emitting electronic products, consulting with TEPRSSC is a means for FDA to obtain expert feedback on its determination that performance standards are necessary to minimize unnecessary radiation. Although there are vacancies on the Committee, FDA is working to fill the vacancies.

In conclusion, FDA is conducting the necessary activities to study and evaluate emissions

⁶¹ See, e.g., National Council on Radiation Protection and Measurements. Routine Gonadal Shielding of Patients During Abdominal and Pelvic Radiography. NCRP Statement No. 13. Bethesda, MD: National Council on Radiation Protection and Measurements, 2021, available at <https://ncrponline.org/wp-content/themes/ncrp/PDFs/Statement13.pdf>.

⁶² See, e.g., Miller DL. Radiation safety in pediatric interventional radiology. Chapter 8. In: Pediatric Interventional Radiology with Surgical Correlations. Tisnado J, Haynes JH, Quevedo E, eds. Lima: Tisnado Medical Editions; 2021; pp. 127-148. ISBN 978-612-48467-0-0.

⁶³ See, e.g., MRI Safety Posters, available at <https://www.fda.gov/radiation-emitting-products/mri-magnetic-resonance-imaging/mri-safety-posters>.

⁶⁴ Interagency Steering Committee on Radiation Standards (ISCORS), available at <https://www.epa.gov/iscors>.

⁶⁵ Conference of Radiation Control Program Directors (CRCPD), available at <https://crcpd.org/>.

⁶⁶ National Council on Radiation Protection & Measurements, available at <https://ncrponline.org/>.

⁶⁷ International Commission on Non-Ionizing Radiation Protection, available at <https://www.icnirp.org/en/about-icnirp/commission/index.html>.

⁶⁸ See, e.g., letter from FDA to FCC, Apr. 24, 2019, available at <https://www.fda.gov/media/135022/download>.

⁶⁹ See, e.g., Memorandum of Understanding (MOU) between the U.S. Department of Health and Human Services, Food and Drug Administration (FDA), and the U.S. Department of Transportation, Federal Aviation Administration (FAA), available at <https://www.fda.gov/about-fda/domestic-mous/mou-225-99-6000>.

⁷⁰ See, e.g., EPA, Interagency Working Group on Medical Radiation, Federal Guidance Report No. 14. "Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures," 2014, available at <https://www.epa.gov/sites/production/files/2015-05/documents/fgr14-2014.pdf>.

⁷¹ See Section 534(f) of the FD&C Act; 21 CFR 14.122(a)(3).



of, and conditions of exposure to, electronic product radiation and intense magnetic fields, including with respect to non-ionizing and non-medical radiation emitting products.

c. FDA Conducts Ongoing Development, Testing, and Evaluation of the Effectiveness of Procedures and Techniques for Minimizing Exposure to Electronic Product Radiation.

Your third request is that FDA take actions to comply with 21 U.S.C. 360ii(a)(5) [section 532(a)(5) of the FD&C Act], and “develop or cause to be developed techniques for minimizing the public’s exposure to non-ionizing radiation from the full array and aggregate emissions of electronic products to which people are exposed, and produce and make public regularly updated information detailing the agency’s actions that demonstrate compliance with the law.”⁷² Your petition asserts that section 532(a)(5) of the FD&C Act requires FDA to work with manufacturers, businesses, and other institutions to develop “plans, procedures, strategies, and techniques” to minimize public exposure to non-ionizing radiation from consumer products. You provide examples of such plans or procedures that “might include working with wireless device manufacturers to provide a one-button disconnect that would immediately disable all wireless antennas,” encouraging colleges and universities to “set aside spaces where non-ionizing radiation is minimized,” developing procedures for “new cars [to] be outfitted with a switch to turn off all unnecessary wireless circuits,” or procedures for “routers [to] be manufactured with circuits to automatically turn off when not in use or at night when users are asleep.”⁷³ You also provide a variety of suggestions for FDA to develop specific procedures and techniques to minimize exposure to harmful radiation, including proposing that “[p]ublic buildings could provide radiation-free zones for citizens. Colleges and universities could be encouraged to set aside spaces where non-ionizing radiation is minimized. Hotels could be encouraged to provide ‘Wi-Fi-free’ rooms for individuals who suffer from electromagnetic sensitivity. All wireless devices, including cell phones, could be required to include more prominent consumer warnings about the hazards of exposure. FDA could engage with companies that provide shielding materials to reduce the transmission of radiation through walls and windows, and those that create equipment to test and monitor for radiation levels.”⁷⁴

We disagree with your assertion that FDA “has failed to engage in any of these, or other similar activities that meet even the minimum requirements of the law.”⁷⁵ Section 532(a)(5) of the FD&C Act directs FDA to develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation. However, the Radiation Control provisions do not require the EPRC program to focus on specific electronic product types, engage with specific stakeholders to develop specific plans, or promulgate specific procedures, strategies, and techniques, including specific performance standards. As noted above, FDA generally focuses on product types that are believed to present greater risk to public

⁷² Petition, p. 15.

⁷³ Petition, pp. 13-14.

⁷⁴ Petition, p. 14.

⁷⁵ *Id.*

health. The Agency conducts ongoing development, testing, and evaluation activities across a variety of product types, including with respect to non-ionizing and non-medical electronic products. FDA continues to collaborate with a variety of stakeholders and industry to research, evaluate, test, and promote the development and adoption of strategies and techniques for minimizing exposure to harmful electronic product radiation, including through guidance recommendations, issuance of regulations, stakeholder engagement, and compliance and enforcement activities, among others.⁷⁶ For example, FDA partners and works with external stakeholders, such as the American College of Radiology, the American Association of Physicists in Medicine, Advanced Medical Technology Association, the Conference of Radiation Control Program Directors (CRCPD), the National Council of Radiation Protection and Measurements (NCRP), that undertake activities aligned with FDA's actions to study, develop, test, and evaluate the effectiveness of procedures and techniques to minimize exposure to electronic product radiation.^{77,78,79,80,81,82} FDA also contributes to the funding, development, and dissemination of critical publications, which provide essential information to guide strategic development of national standards and safety initiatives, such as funding efforts by the Image Gently Alliance and CRCPD.^{83,84}

IV. Conclusion

For the reasons set forth above and in accordance with 21 CFR 10.30(e)(3), FDA is denying your request.

FDA takes safety concerns regarding electronic product radiation seriously. FDA has been and continues to monitor impacts to public health and safety from radiation-emitting products consistent with the Radiation Control provisions.

⁷⁶ See, e.g., 21 CFR 1002.1(a), 1002.20; 21 CFR part 1003, including 21 CFR 1003.11(a) regarding testing; Section 535 of the FD&C Act; see also example activities described in Sections III(a) and (b) above.

⁷⁷ American College of Radiology, ACR Statement on FDA Radiation Reduction Program, Feb. 10, 2011, available at <https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/FDA-Radiation-Reduction-Program>.

⁷⁸ American Association of Physicists in Medicine, Government Affairs, available at https://www.aapm.org/government_affairs/default.asp.

⁷⁹ AdvaMed Medical Imaging Standards, May 22, 2024, available at <https://www.advamed.org/member-center/resource-library/advamed-medical-imaging-standards/>.

⁸⁰ Conference of Radiation Control Program Directors (CRCPD), available at <https://crcpd.org/>.

⁸¹ See, e.g., National Council on Radiation Protection and Measurements. Recommendations for Stratification of Equipment Use and Radiation Safety Training for Fluoroscopy. Commentary No. 33. Bethesda, MD: National Council on Radiation Protection and Measurements, 2023, available at <https://ncrponline.org/shop/commentaries/commentary-no-33/>.

⁸² See, e.g., SC 8-1: Development of NCRP Informational Webpages to Provide Authoritative Information About the Use of Wireless Technology and Current Evidence on Health Effects <https://ncrponline.org/program-areas/sc-8-1/>.

⁸³ See, e.g., Image Gently and Digital Radiography - Quality Improvement, available at <https://www.imagegently.org/Procedures/Digital-Radiography/Quality-Improvement>.

⁸⁴ See, e.g., Funding Opportunity: Assuring Radiation Protection: [RFA-FD-18-021: Assuring Radiation Protection \(U18\)](https://www.fda.gov/oc/foia/2018-0018).



If you have any questions about this response, please contact Rachel Park at rachel.park@fda.hhs.gov.

Sincerely,

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