May 23, 2022

Douglas A. Wood
Founder and National Director
Americans for Responsible Technology
184 Main Street
Port Washington, NY

Re: Citizen Petition – Docket Number FDA-2021-P-1347

Dear Mr. Wood:

This letter responds to your citizen petition received on December 21, 2021, requesting the Food and Drug Administration (FDA) declare an Imminent Hazard regarding the use of radiofrequency products such as cell phones. 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).

A. Action Requested

In your petition, you request the Health and Human Services Secretary:

(i) declare an Imminent Hazard on an expedited basis based on the apparent absence of official standards as well as continued misstatements, made by many commentors and decisions makers, that FDA has established RF safety standards through required administrative procedures, when nothing in the public record establishes that it has adopted such standards; and

(ii) promptly work to ensure that this declaration is communicated affirmatively to all public and private entities that are impacted by the Imminent Hazard.

B. Legal Background

FDA regulates several products categories, including devices and radiation-emitting electronic products, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under the FD&C Act, a device is:

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –
>
> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplements to them,

> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (C) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

FD&C Act § 201(h)(1).

FDA is also 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for regulating radiation-emitting electronic products through the Radiation Control provisions of the FD&C Act (originally enacted as the Radiation Control for Health and Safety Act of 1968), which are in sections 531 through 542 of the FD&C Act ("Radiation Control provisions").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".

FD&C Act § 531(2).

Chapter V, Subchapter C of the FD&C Act (sections 531-542) includes imports, inspections, reporting, prohibited acts, and enforcement provisions for electronic products.

Some products may be both devices within the meaning of section 201(h) and electronic products within the meaning of section 531, such as X-ray machines. Such products are subject to both FDA's device laws and regulations and FDA's electronic product laws and regulations. Other electronic products, however, such as microwaves, are not devices within the meaning of section 201(h) and therefore are only subject to FDA's electronic product laws and regulations.

In your petition, you request that the HHS Secretary declare an imminent hazard concerning radio frequency (RF) emissions of cell phones, among other products, pursuant to 21 CFR 2.5, which states:

> "(a) Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is

> sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation
>
> (1) that should be corrected immediately to prevent injury and
>
> (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The imminent hazard may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an imminent hazard of such occurrence exists.
>
> (b) In exercising his judgment on whether an imminent hazard exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury."

21 CFR 2.5.

21 CFR 2.5 is a regulatory definition and is only relevant to explain the term "imminent hazard to the public health" where that term appears in the FD&C Act. While some FD&C Act provisions governing drugs, devices, animal drugs, and foods use the phrase "imminent hazard to the public health," [1] no provision in Chapter V, Subchapter C of the FD&C Act, which governs electronic products, uses that term. As a result, 21 CFR 2.5 does not apply to electronic products, unless the product is also a device as defined in section 201(h) and an FD&C Act provision relevant to the regulation of such device uses the phrase "imminent hazard to the public health."[2]

C. Discussion

The products cited in your petition are electronic products within the meaning of section 531 of the FD&C Act, and therefore 21 CFR 2.5 does not apply to them. Further, no FD&C Act provision outside of Chapter V, Subchapter C that uses the phrase "imminent hazard to the public health" (e.g., a device FD&C Act provision) also applies to the products.[3] We note that

[1] Some FD&C Act provisions governing drugs, devices, animal drugs, and foods contain the phrase, "imminent hazard to the public health." See, e.g., sections 505, 505G, 512, and 707 of the FD&C Act.

[2] The regulatory history of 21 CFR 2.5 provides further support that 21 CFR 2.5 does not apply to electronic products unless a separate statutory provision, e.g., a provision for devices, also applies to the product. When 21 CFR 2.5 was promulgated (see 36 Fed. Reg. 12516-17 (Jul. 1, 1971) (originally codified at 21 CFR 3.73)), the preamble to the final rule stated that "the definition of 'imminent hazard' is meant to apply to, and does apply to, all products subject to the [FD&C Act] and the Federal Hazardous Substances Act." 36 FR 12516. At that time, the Electronic Product Radiation Control provisions were contained in the Public Health Service Act (PHSA)—not the FD&C Act, and therefore were not subject to 21 CFR 2.5. Further, FDA has proposed to revoke 21 CFR 2.5 twice (in August 1979 (see 44 Fed. Reg. 48983 (Aug. 21, 1979)) and in January 1994 (see 59 Fed. Reg. 3042 (Jan. 20, 1994)), but FDA decided to retain the regulation "to continue providing guidance in interpreting these and other provisions in the act and FDA regulations." 62 Fed. Reg. 39439 (July 23, 1997). This history further supports that 21 CFR 2.5 is relevant only when the term "imminent hazard to the public health" appears in the FD&C Act.

[3] Your petition mentions smartphones, Wi-Fi routers, cell towers, rooftop and pole mounted antennas, over-the-air reception devices, and domestic wireless devices such as "household surveillance cameras, heating and cooling controls, smart meters, and major and even minor appliances such as coffeemakers which are now dubbed 'smart devices'" among other "wireless devices and systems." These products do not meet the definition of device under

you did not cite any FD&C Act provision using the term "imminent hazard to the public health" that applies to the products you mention. Because the products cited in your petition are solely electronic products governed by Chapter V, Subchapter C of the FD&C Act, and 21 CFR 2.5 is not a part of the legal framework of Chapter V, Subchapter C of the FD&C Act, FDA cannot take the action requested.

D. Conclusion

For the reasons discussed above, your petition is denied under 21 CFR 10.30(e)(3).

Sincerely,

Ellen J. Flannery -S

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Date: 2022.05.23 14:17:25 -04'00'

Ellen J. Flannery, JD
Deputy Center Director for Policy
Center for Devices and
Radiological Health

section 201(h) of the FD&C Act because they are not "[i]ntended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals" or "[i]ntended to affect the structure or any function of the body of man or other animals" (section 201(h) of the FD&C Act). Some of the products mentioned in your petition may serve as a platform for a device; for example, a smartphone may be a platform for a mobile medical application that is a device (e.g., a mobile medical app that controls the delivery of insulin for an insulin pump). In this example, however, the smartphone itself is not a device within the meaning of section 201(h)—only the mobile medical app is a device. For more information on FDA regulation of mobile medical applications, see FDA's Final Guidance, Policy for Device Software Functions and Mobile Medical Applications (Sept. 2019), available at https://www.fda.gov/media/80958/download.