U.S. FOOD & DRUG ADMINISTRATION

JUL 17 2017

Frederick S. Mayer, R.Ph., M.P.H.
President, Pharmacists Planning Service, Inc.
101 Lucas Valley Road, Suite 386
San Rafael, California 94903

Re: Citizen Petition – Docket Number FDA-2013-P-1374

Dear Mr. Mayer,

This letter responds to the above referenced citizen petition, dated October 4, 2013, and filed with the U.S. Food and Drug Administration (FDA) on November 20, 2013. You also filed additional materials to supplement your petitions 28 times, and your last supplemental material was received on May 22, 2017. We have carefully reviewed the materials and arguments set forth in your citizen petition and supplemental filings, and for the reasons outlined below, we deny the petition to the extent that any requests in the petition are not already moot due to actions that have already been undertaken or are being undertaken, as explained below.

A. Petition

In your petition, you request that the Commissioner of the FDA hold public hearings to establish an electronic product radiation safety performance standard applicable to cell phones. In the petition, you specifically listed the following items:

> *"1) Consumers have a right to know the level of radiation their phones emit.*
>
> *2) Latest science points to potential risk to children's health.*
>
> *3) Federal standards for cell phone radiation need to be modernized from 1996.*
>
> *4) What consumers can do to reduce exposures to cell phone radiation.*
>
> *5) Education and awareness campaign to alert consumers of the WHO warnings.*
>
> *6) Hold public hearings and open up a Federal Registry on the entire RFR/EMF health issues.*
>
> *7) Print in 12 point font warning notices to consumers purchasing wireless devices."*

B. Moot Petition Requests

The first six requests that are listed above are moot as the following independent actions relevant to these requests have already been undertaken, or are currently being undertaken, by the FDA, the

Federal Communications Commission (FCC), and/or others:

1) **Consumers have a right to know the level of radiation their phones emit**. As we understand the request, you are asking that the information on the specific absorption rate (SAR) of a cell phone be made known to the public. This information is already available to the public. The FCC maintains an SAR database at: https://www.fcc.gov/oet/ea/fccid. A phone's SAR can be found by entering the phone's FCC ID number. It has already been determined, however, that the SAR, reported for a specific phone model as the maximum value generated under worst case conditions, does not usually represent the normal emission rate of a phone. Phones with higher SARs that still comply with FCC requirements will on average expose their users to less radiofrequency (RF) energy. Thus, SAR is not a useful indicator of emissions and using it as a way to determine purchases may have the opposite effect – i.e., it could drive the industry to optimize its maximum SAR rather than optimizing the performance of the phone by lowering the cell phone's emissions and thereby increasing the battery life. The FCC has posted a web page at: https://www.fcc.gov/consumers/guides/specific-absorption-rate-sar-cell-phones-what-it-means-you that provides information about the meaning of a phone's SAR compliance value.

2) **Latest science points to potential risk to children's health.** There are several ongoing epidemiology studies involving children and radiation exposure from cell phones and this has been included on our web page to educate the public. See http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116331.htm.

3) **Federal standards for cell phone radiation need to be modernized from 1996**. FCC determined that modernization should be considered and independently issued a Notice of Inquiry regarding their RF exposure policy on March 29, 2013. For more information see the FCC webpage titled, "FCC Review of RF Exposure Policies" at: https://www.fcc.gov/document/fcc-review-rf-exposure-policies

4) **What consumers can do to reduce exposures to cell phone radiation.** The information for reduction in exposure from possible cell phone radiation is provided on our web pages (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116282.htm).

5) **Education and awareness campaign to alert consumers of the WHO warnings.** The World Health Organization (WHO) has not issued a warning. An agency of WHO (International Agency for Research on Cancer) has issued an analysis based on very weak evidence that it might be possible there might be a risk.

6) **Hold public hearings and open up a Federal Registry on the entire RFR/EMF health issues.** In 2013, the FCC undertook this process by issuing the proposed rule entitled "In the Matter of Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency", ET Docket No. 03-137, and Notice of Inquiry entitled "In the Matter of Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies", ET Docket No. 13-84, FCC 13-39,(adopted

March 27, 2013 and released March 29, 2013) available at https://www.fcc.gov/general/radio-frequency-safety-0. Comment was later sought via publication of summaries of these proposals in the

Federal Register along with request for comment. See 78 FR 33654 (June 4, 2013); (https://www.regulations.gov/document?D=FCC-2013-0212-0002). Please also refer to the regulations.gov docket FCC-2013-0212. The public comment period was from June 4, 2013 to September 3, 2013.

C. Establishment of Performance Standards for Electronic Products

Your seventh request is that we print in 12 point font warning notices to consumers purchasing wireless devices. However, in order to require specific labeling, a performance standard relevant to the labeling must have been established based on the relevant statutory criteria. There is no basis for establishment of such a performance standard.

Specifically, the criteria for establishment of a new radiation safety performance standard for electronic products is found in the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), section 534(a)(1), which states as follows:

> The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation **from such products if he determines that such standards are necessary for the protection of the public health and safety**. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products.

21 U.S.C. § 360kk(a)(1) (emphasis added). The specific criterion to begin the establishment of a performance standard is the determination that a standard is "necessary for the protection of the public health and safety." As explained below, this criterion has not been met.

D. Scientific and Medical Data

The information you provided is not adequate to demonstrate that action is necessary for the protection of public health and safety. For the development of a new radiation safety performance standard for electronic products, FDA considers the vast body of relevant data, including the latest available scientific and medical data in the field of electronic product radiation, among other things. *See* 21 U.S.C. 360kk(a)(1). Further, FDA continuously monitors the latest available scientific and medical data in this field. The scientific and medical data on this topic does not demonstrate that exposure to radiofrequency (RF) energy at or below accepted safety limits causes adverse health effects. Many expert reports have been released that discuss the strengths and weaknesses of the published literature[1],[2]. There have also been formal analyses and reviews of published expert reports[3],[4]. The foot-noted documents are examples, and not exhaustive lists, of such reports. FDA will

[1] The World Health Organization (WHO) International Agency for Research on Cancer (IARC) (2013) Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 102. Radiofrequency Electromagnetic Fields.
[2] SCENIHR (2015) Opinion on Potential health effects of exposure to EMF.

[3] Verschaeve, L. (2012). Evaluations of International Expert Group Reports on the Biological Effects of Radiofrequency Fields, Wireless Communications and Networks - Recent Advances, Dr. Ali Eksim (Ed.). Wireless Communications and Networks - Recent Advances. A. Eksim, InTech.

continue to monitor developments in science related to RF emissions from consumer communication electronic products to determine if our conclusions regarding exposure to cell phone radiation should be modified. FDA's website at http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116282.htm provides significant information about FDA's current thinking on cell phones and RF exposure.

Based on the scientific and medical data currently available, FDA has concluded that exposure to RF energy at or below accepted safety limits does not cause or contribute to adverse health effects. Given the discussion above and the lack of any adequate supporting information in your petition, FDA does not believe establishment of a new radiation safety performance standard for consumer communication electronic products is necessary for the protection of the public health and safety, as required by the FD&C Act. *See* 21 U.S.C. 360kk(a)(1). Accordingly, we believe a public hearing is not necessary.

E. Conclusion

Your citizen petition, which was filed under 21 C.F.R. § 10.20 and § 10.30 and requests FDA to take several actions, that either have been taken, are being taken, or are not supported by the available science. FDA cannot require industry to take action in regard to electronic products under a particular performance standard without a demonstration that such a standard is necessary for the protection of the public health and safety. Your citizen petition does not provide adequate information to support the establishment of a standard based on the relevant statutory criteria. Accordingly, FDA is denying your citizen petition to the extent that any of the requests in your petition are not already moot due to actions that have already been undertaken or are being undertaken, as explained above.

If you have any questions, please contact Mr. Madhusoodana Nambiar by e-mail at madhusoodana.nambiar@fda.hhs.gov or 301-796-5837.

Sincerely yours,

Jeffrey Shuren, MD, JD
Director
Center for Devices and Radiological Health
Food and Drug Administration

[4] Scarfi, M. R. and Vijayalaxmi (2014). "International and national expert group evaluations: biological/health effects of radiofrequency fields." International journal of environmental research and public health 11(9): 9376-9408.