August 23, 2007

4645 7 AUG 27 A10:05

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under Federal Food, Drug and Cosmetic Act (FFDCA), Chapter V, Subchapter C - Electronic Product Radiation Control Radiation Control Law (Federal FD&C Act), Safe Medical Devices Act of 1990 of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to .

A. ACTION REQUESTED

1. Strict and immediate enforcement of the performance standards contained in 21CFR sections 1020.30(g)(h) and 1020.33(c in sequence)
2. Strict and immediate enforcement of the performance standards contained in 21CFR 1040.10(h in sequence)
3. Strict and immediate enforcement of 21CFR 820.170 requiring manufacturers to supply all information for installations of all installable medical devices regardless of whether the installation is the first installation or not of the device
4. A means to calculate Computed Tomography dosage index, dose profile and dosage measurement for a dual tube CT system as prescribed in 21CFR 1020.30 (c in sequence)
5. A public response from the FDA assuring the public that the FDA will strictly enforce the laws of this Nation for all medical devices in the future.

B. STATEMENT OF GROUNDS

21 U.S.C Chapter V Subchapter C, Federal Food, Drug and Cosmetic Act gives the FDA the authority to regulated all medical devices that produce "electronic product radiation"

2007P-0333

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The action requested in Section A 1, 2 and 4 are subject to 21 U.S.C Chapter V Subchapter C.

The FDA has the power and the responsibility to protect all American from the "inherent dangers", as described by the FDA, of ionizing radiation (x-rays) within 21 U.S.C Chapter V Subchapter C without any new laws or discussion.

It is my understanding that unnecessary deaths of children, elderly and small adults are occurring every year due to the radiation that CT Scanners produce and possibly other devices that are not installed properly.

I believe all Americans support all efforts to keep the most vulnerable members of our society safe from any unnecessary risks, which can be prevented by enforcing current laws.

C. ENVIRONMENTAL IMPACT STATEMENT

There is no known environmental impact what so ever.

Enforcement by the FDA of existing laws can save lives, which may burden the environment more.

D. ECONOMIC IMPACT STATEMENT

Lowering healthcare cost by possibly a reduction of after warranty costs to all facilities using medical devices.

There is no known economic determent to the economy or the ~~citizens~~ of the U.S.

Thomas J Quinn

Name of Petitioner

Signature

411 TYBURN Rd Uwchland PA. 19480

Address

[redacted]

(Phone)

August 23, 2007

6858 7 AUG 27 A10:59

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857

CITIZEN PETITION

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E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Thomas J Quinn

Name of Petitioner

Signature

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[redacted]

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