



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 19, 2007

FILE COPY

Rebecca Gilbert
898 McMeekin Place
Lexington, KY 40502

Dear Ms. Gilbert:

Your petition requesting the Food and Drug Administration to enforce performance standards contained in 21 CFR 10.20(g)(h), 1020.33(c) and 21 CFR 1040.10(h); enforce 21 CFR 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; a means to calculate Computed Tomography dosage Index, dose profile and dosage measurement for dual tube CT system as prescribed in 21 CFR 1020.30(c); and a public response assuring that the FDA will strictly enforce the laws for all medical devices in the future, was received by this office on 09/18/2007. It was assigned docket number 2007P-0333/CP7 and it was filed on 09/18/2007. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Lyle D. Jaffe".

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2007P-0333

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