Food and Drug Administration, HHS

§ 1010.4 Variances.

(a) Criteria for variances. (1) Upon application by a manufacturer (including an assembler), the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant a variance from one or more provisions of any performance standard under subchapter J of this chapter for an electronic product subject to such standard when the Director determines that granting such a variance is in keeping with the purposes of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968), and:

(i) The scope of the requested variance is so limited in its applicability as not to justify an amendment to the standard, or

(ii) There is not sufficient time for the promulgation of an amendment to the standard.

(2) The issuance of the variance shall be based upon a determination that:

(i) The product utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard, or

(ii) The product performs a function or is intended for a purpose which could not be performed or accomplished if required to meet the applicable standards, and suitable means for assuring radiation safety or protection are provided, or

(iii) One or more requirements of the applicable standard are not appropriate, and suitable means for assuring radiation safety or protection are provided.

(b) Applications for variances. If you are submitting an application for variances or for amendments or extensions thereof, you must submit an original and two copies to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(1) The application for variance shall include the following information:

(i) A description of the product and its intended use.

(ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(iii) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard.

(iv) A description of the advantages to be derived from such deviation.

(v) An explanation of how alternate or suitable means of radiation protection will be provided.

(vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture.
§ 1010.5 Exemptions for products intended for United States Government use.

(a) Criteria for exemption. Upon application by a manufacturer (including assembler) or by a U.S. department or agency, the Director, Center for Devices and Radiological Health, Food