Food and Drug Administration, HHS

Support required to equal to 1 man-year .......................... 2,256
Equivalent gross annual working hours charged to Food and Drug appropriation ...................................... 4,512

NOTE: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours (4512/1696)=266 pct.

(d) The minimum charge for services of supervising officers shall be not less than the charge for 1 hour and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

§ 1005.25 Service of process on manufacturers.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer’s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) 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) (21 U.S.C. 360mm(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

(b) A manufacturer designating an agent must address the designation to the Center for Devices and Radiological Health (HFZ–240), 9200 Corporate Blvd., Rockville, MD 20850. It must be in writing and dated; all signatures must be in ink. The designation must be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation must disclose the manufacturer’s full legal name and the name(s) under which the manufacturer conducts the business, if applicable, the principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation must identify the marks, trade names, or other designations of origin which these products bear. The designation must provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent must be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section.

(c) Service of any process, notice, order, requirement, or decision specified in section 536(d) 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) (21 U.S.C. 360mm(d)) may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 536(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Center for Devices and Radiological Health and publishing a notice that such service was made in the Federal Register.

§ 1005.25.1 Scope.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer’s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) 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) (21 U.S.C. 360mm(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

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(c) Service of any process, notice, order, requirement, or decision specified in section 536(d) 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) (21 U.S.C. 360mm(d)) may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 536(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Center for Devices and Radiological Health and publishing a notice that such service was made in the Federal Register.