§ 1141.12 Incorporation by reference of required warnings.

“Cigarette Required Warnings” Edition 1.0 (June 2011), consisting of electronic files, U.S. Food and Drug Administration, referred to at §1141.3, §1141.10(a) and (b), and §1141.16(a), is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Also, you may obtain a copy of the material by contacting the Center for Tobacco Products, Food and Drug Administration, Office of Health Communication and Education, ATTN: Cigarette Warning File Requests, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373, or cigarettewarningfiles@fda.hhs.gov. You may also obtain the material at http://www.fda.gov/cigarettewarningfiles.

§ 1141.14 Misbranding of cigarettes.

(a) A cigarette shall be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(b) A cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

§ 1141.16 Disclosures regarding cessation.

(a) The required warning shall include a reference to a smoking cessation assistance resource in accordance with, and as specified in, “Cigarette Required Warnings” (incorporated by reference at §1141.12).