(9) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of §25.40 of this chapter.

(c) *Exemption determination.* FDA will review the information submitted and determine whether to grant or deny an exemption request based on whether the criteria in section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act are met. FDA may request additional information if necessary to make a determination. FDA will consider the exemption request withdrawn if the information is not provided within the requested timeframe.

(d) *Rescission of an exemption.* FDA may rescind an exemption if it finds that the exemption is not appropriate for the protection of public health. In general, FDA will rescind an exemption only after notice and opportunity for a hearing under part 16 of this chapter is provided. However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 of this chapter if the continuance of the exemption presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

Subpart B [Reserved]

PART 1140—CIGARETTES AND SMOKELESS TOBACCO

SUBPART A—GENERAL PROVISIONS

Sec.

1140.1 Scope.
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SUBPART B—PROHIBITION OF SALE AND DISTRIBUTION TO PERSONS YOUNGER THAN 18 YEARS OF AGE

1140.10 General responsibilities of manufacturers, distributors, and retailers.
1140.12 Additional responsibilities of manufacturers.
1140.14 Additional responsibilities of retailers.
1140.16 Conditions of manufacture, sale, and distribution.

SUBPART C [RESERVED]

SUBPART D—LABELING AND ADVERTISING

1140.30 Scope of permissible forms of labeling and advertising.
1140.32 Format and content requirements for labeling and advertising.
1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

AUTHORITY: 21 U.S.C. 301 *et seq.*, Sec. 102, Pub. L. 111–31, 123 Stat. 1776.

SOURCE: 75 FR 13230, Mar. 19, 2010, unless otherwise noted.

Subpart A—General Provisions

§1140.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§1140.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§1140.3 Definitions.

(a) *Cigarette.* (1) Means a product that:

(i) Is a tobacco product; and

(ii) Meets the definition of the term ''cigarette'' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the