

Summary of the Deeming Proposed Rule

FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. In this rule, FDA is proposing two options for deeming products to be subject to the tobacco product authorities in Chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Option 1 would extend the Agency's "tobacco product" authorities in the FD&C Act to all categories of products, except accessories of a proposed deemed tobacco product, which meet the statutory definition of "tobacco product" in the FD&C Act. Option 2 would extend the Agency's "tobacco product" authorities to a subset of cigars (referred to as "covered cigars") as well as other products meeting the definition of "tobacco product," except the accessories of a proposed deemed tobacco product.¹

These newly regulated products would include currently marketed products such as electronic cigarettes, cigars², pipe tobacco, and hookah tobacco, as well as future tobacco products. Such tobacco products would be required to comply with all provisions regarding "tobacco products" found in the FD&C Act ("automatic provisions"). In addition, a subset of these products (referred to as "covered tobacco products"), would be subject to certain additional restrictions. These automatic provisions and additional restrictions, as well as the timeframes for complying with these requirements, are discussed below.

Automatic Provisions

Newly deemed tobacco products would automatically be required to comply with all provisions regarding "tobacco products" found in the FD&C Act. Based on these automatic provisions, this rule would require industry, which includes Tribal manufacturers and retailers (where applicable), to take certain actions, such as:

1. Ensure that tobacco products are not adulterated or misbranded
2. Provide FDA with ingredient listings for all tobacco products
3. Register and provide FDA with product listings for all tobacco products

¹ As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

² Under Option 1, all cigars would be regulated. Under option 2, "covered cigars" would be regulated. This rule proposes to define "covered cigar" as: any cigar as defined in this part, except a cigar that:

- (1) Is wrapped in whole tobacco leaf;
- (2) Contains a 100 percent leaf tobacco binder;
- (3) Contains primarily long filler tobacco;
- (4) Is made by combining manually the wrapper, filler, and binder;
- (5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;
- (6) Has a retail price (after any discounts or coupons) of no less than ten dollars per cigar (adjusted, as necessary, every two years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment, as measured by the Consumer Price Index for Tobacco and Smoking Products);
- (7) Does not have a characterizing flavor other than tobacco; and
- (8) Weighs more than six pounds per thousand units.

4. Eliminate the use of modified risk descriptors and claims unless FDA issues an order permitting their use
5. Follow one of the pathways to market for newly deemed products that meet the definition of “new tobacco product” as specified in the Food, Drug & Cosmetic Act

Additional Restrictions

FDA also proposes to add these three restrictions to “covered tobacco products.”³

1. Requirement for a minimum age of purchase
2. Prohibition of vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time.
3. Health warnings for product packages and advertisements
 - A. FDA is proposing a warning regarding the addictiveness of nicotine to apply to all covered tobacco products – “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical⁴.”
 - FDA is proposing a self-certification option for manufacturers who certify that their product does not contain nicotine (and that they have data to support that assertion). Such a product would be required to bear the statement, "This product is derived from tobacco."
 - B. FDA also is proposing four health warnings for cigars, which were included in the Federal Trade Commission consent agreements with the major cigar manufacturers signed in 2000. These warnings are:
 - WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
 - WARNING: Cigar smoking can cause lung cancer and heart disease.
 - WARNING: Cigars are not a safe alternative to cigarettes.
 - WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
 - C. FDA is also proposing a different labeling rule for premium cigars and other cigars that are sold individually and not in a product package. Health warnings for such cigars would be displayed on a sign which would be posted at the point-of-sale of any retail establishment.

Effective and Compliance Dates

FDA is proposing an effective date of 30 days from the date of publication of the final rule for the part of the regulation that deems products to be subject to the FD&C Act, and for the age, ID, and vending machine restrictions.

³ FDA is proposing to define “covered tobacco product” as any tobacco product deemed to be subject to the Federal Food, Drug & Cosmetic Act pursuant to [proposed] § 1100.2 of title 21 of the Code of Federal Regulations, but excludes any component or part, that does not contain tobacco or nicotine.

⁴ Under option 2, only “covered cigars” would be required to use this warning.

| Provision | Effective Date |
|--------------------------------------|---|
| Minimum age of sale | 30 days from the date of publication of the final rule |
| Prohibition of vending machine sales | 30 days from the date of publication of the final rule |
| Health Warning Requirements | 24 months after publication of the final rule, with a 30-day sell off period for existing merchandise |

However, we are also proposing compliance dates for certain automatic provisions that would require labeling changes or information submissions to the Agency to give regulated industry time to comply with such provisions, including:

| Provision | Compliance Date (upon publication of final rule) |
|--|--|
| Ingredient reporting | Effective date plus 6 months or 90 days prior to marketing |
| Submission of health information | Effective date plus 6 months or 90 days prior to marketing |
| Premarket tobacco product applications | Effective date plus 24 months |
| SE submissions | Effective date plus 24 months |
| Preventing misleading claims and descriptors by prohibiting all claims of modified risk that are not based on scientific evidence and reviewed and authorized by FDA | Effective date plus 12 months to stop manufacturing; Effective date plus 13 months to stop distribution |
| Reporting of HPHCs | Effective date plus 3 years |
| Establishment of registration and product listing submissions | Date will be specified in a new draft guidance |