

THE LETTER OF THE LAW

How FDA regulation will impact your business

By Brian Malkin

Commentators from all sides of the tobacco debate have shared their opinions on the recent enactment of the Family Smoking Prevention and Tobacco Control Act. The views expressed range from elated to outraged and everything in between. But what exactly does the act call for? Brian Malkin, partner in the New York office of Frommer Lawrence & Haug LLP, has closely examined the text. In this article, he explains how it will affect your business.



All of these new authorities are linked to the FDA's mission to protect public health with a new goal to reduce tobacco product use by minors. Within the FDA, a new center, called the Center for Tobacco Products, will soon be established to implement and oversee the FDA's new regulatory authorities. The tobacco act requires the FDA to re-issue within a year its 1996 final regulations restricting the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products. (These regulations had previously been struck down by the Supreme Court.) The rule contains provisions to limit minors' access to tobacco products and restricts marketing to reduce its initial appeal to minors.

On June 22, 2009, President Obama signed into law the landmark Family Smoking Prevention and Tobacco Control Act, which grants the FDA new authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) to regulate the manufacture, marketing and distribution of tobacco products. In the tobacco act, Congress explicitly describes the FDA as the primary federal regulatory authority for tobacco products.

The tobacco act provides the FDA with sweeping authority to require tobacco manufacturers to disclose ingredients and additives in their tobacco products; establish standards or reductions for certain ingredients in tobacco products; restrict sales, distribution, advertising and promotion of tobacco products; and require stronger and more prominent health warnings on the packaging of tobacco products. The FDA also has the authority to regulate new "modified risk" tobacco products and establish appropriate standards for their approval.

FDA actions to date

On July 1, 2009, the FDA published a federal register notice requesting general comments regarding how the FDA should approach its new regulatory authorities, requesting comments be filed by Sept. 29, 2009, to its Division of Dockets Management, FDA, 5630 Fishers Lane, HFA-305, Room 1061, Rockville, MD 20852. The docket number is FDA-2009-N-0294 and may be found by inserting this number in the search field of www.regulations.gov. The FDA stated that, in the future, it would solicit comments on specific topics.

The FDA has established on its Web site (www.fda.gov) a new link for tobacco products, www.fda.gov/TobaccoProducts/default.htm, which includes information about the tobacco act, health news from the Centers for Disease Control and other health authorities, and resources and information to help individuals quit smoking. The portal also includes initial contact information for the FDA. ►

A quick guide to key sections of the tobacco act

Section 2. Findings

Congress included 49 findings in the act, including the facts that nicotine is addictive, tobacco use is dangerous and that marketing has been directed to attract younger persons to tobacco products. Congress determined that the FDA's proposed final rule in 1996 was legal and that less restrictive approaches have not been effective. Congress also determined that the FDA should conduct pre-market reviews for reduced-risk tobacco products and only approve such products that benefit the population as a whole, because it believes the only safe alternative to smoking is quitting.

Section 3. Purpose

Congress identified 10 main goals of the tobacco act. These goals are to provide the FDA with authority under the FFDCA to regulate the manufacture, marketing and distribution of tobacco products. The FDA may reduce the levels of tar, nicotine and other harmful components in tobacco products and set standards for the identity, disclosure and amount of harmful ingredients in tobacco products. The FDA may develop measures to provide consumers with truthful information about tobacco products, while promoting measures to encourage tobacco users to quit using tobacco products and to discourage children from beginning to use them. Additional measures strengthen existing legislation to prevent illicit trade in tobacco products and prevent minors from obtaining such products.

Section 4. Scope and effect

The tobacco act is not intended to affect existing laws set by the secretary of agriculture for the growing, cultivation or curing of raw tobacco or by the Department of the Treasury for revenue collection.

Title I—Authority of the Food and Drug Administration

Section 101. Amendment of Federal Food, Drug, and Cosmetic Act

The FFDCA is amended to include “Chapter IX—Tobacco Products” setting forth various tobacco product-related definitions, specifying the acts that “adulterate” or “misbrand” a tobacco product, and granting the FDA overall regulatory authority over tobacco products. Within 90 days of enactment of the new law, the FDA must establish a Center for Tobacco Products that is responsible for implementing measures described in the tobacco act.

Within six months after enactment, tobacco manufacturers and importers must report to the FDA certain health information and effects for all of their tobacco products, including a list of ingredients; the content, delivery and form of nicotine in milligrams; and health or marketing-related research. Beginning three years after enactment, such information shall include a listing of all constituents of tobacco products, including the smoke, if relevant. Tobacco manufacturers must provide the FDA with at least 90 days advance

notice before increasing the amount of an additive or using a new additive. Within two years after enactment, the FDA will establish a list of harmful and potentially harmful constituents in tobacco products and thereafter place annual updates on public display.

Establishments that manufacture, prepare, compound or process tobacco products, including repackagers, must register annually and report their respective tobacco products biannually. Each establishment may be subject to inspections every two years. The FDA may restrict the sale, distribution, advertising and promotion of tobacco products to protect public health, decrease existing use of tobacco products and prevent individuals from initiating use.

Within six months after enactment, the FDA must establish a Tobacco Products Scientific Advisory Committee that includes 12 members with diversified technical expertise in medicine, medical ethics, science or technology involving the manufacture, evaluation or use of tobacco products. Within the first year after it is formed, the committee must submit to the FDA a report on the use of menthol in cigarettes and its effect on public health. Within the first two years, the committee shall issue a similar report on dissolvable tobacco products.

With the advice of the committee, the FDA is to establish good manufacturing requirements for tobacco products, which may include testing raw tobacco for pesticide residues.

In addition, the FDA must establish cigarette tobacco product standards that prohibit the addition of flavors other than tobacco and menthol within three months after enactment. The standards must also, within two years, prohibit manufacturers from using tobacco that contains pesticide residues higher than a level specified for domestic-grown tobacco.

The FDA may establish additional or amended standards as appropriate to protect the public health, such as reduced nicotine yields, through public rule-making and input from other agencies and informed persons. Once final, such amended or new standards generally will take effect no sooner than one year after publication. The FDA may not, however, ban all cigarettes, smokeless tobacco products, cigars, pipe tobacco or roll-your-own tobacco products, or reduce nicotine yields to zero. The FDA may recall or remove tobacco products with serious or adverse event health risks or for failure to follow the prescribed statutory laws or related FDA regulations.

New tobacco products, defined as products not commercially marketed by Feb. 15, 2007, are subject to premarket review unless substantially similar to a previously marketed product. Modified-risk tobacco products, which do not include smoking cessation products or smokeless tobacco products, are also subject to premarket review and may only be approved if they reduce the harm and risk of tobacco-related disease to individual users and the public as a whole. Currently marketed products labeled with terms such as “light,” “mild” and “low tar” are considered modified-risk products and may no longer

be marketed without such premarket review. Such products may be marketed for five years; approval may be renewed if the conditions for approval continue to be met. The FDA must establish regulations for new and modified-risk tobacco products within two years of enactment.

The FDA shall issue regulations to require certain advertising restrictions for retail establishments for which the predominant business is the sale of tobacco products.

The Federal Trade Commission will retain its jurisdiction and authority for the advertising, sale and distribution of tobacco products and coordinate its efforts with the FDA.

Within three years from enactment the FDA is to issue regulations to require testing and reporting of tobacco product constituents, ingredients and additives, including smoke constituents, which may include disclosures through labels, advertising and other appropriate means. Small tobacco manufacturers have an extended period to comply with the new regulations that the FDA promulgates, in particular testing and reporting.

Certain state and local authorities are retained, such as product liability, whereas the standards addressed in the tobacco act cannot be made more stringent or added to.

The FDA shall fast-track smoking cessation products and consider how to regulate, promote and encourage the development of such products, including both nicotine- and non-nicotine-containing products.

Beginning on the date of enactment, the FDA shall assess user fees from each manufacturer and importer subject to the tobacco act, such totals from all such entities for a fiscal year starting at \$85 million for 2009 and escalating to \$712 million by 2019. The user fee for a particular manufacturer or importer is determined based on market share, and the FDA may only use the collected fees for the regulation of tobacco products or certain start-up costs associated with the FDA's new regulatory authority over tobacco products.

Section 102. Final rule

As soon as possible after six months after enactment, the FDA shall re-publish its 1996 final rule regarding cigarettes and smokeless tobacco. This rule will then become effective one year after enactment of the tobacco act. Added to the rule is a provision that certain "qualified adult-only facilities" may distribute limited quantities of smokeless tobacco to adults, excluding sports teams or entertainment groups.

Section 103. Conforming and other amendments to general provision

This section includes a variety of conforming amendments to add tobacco products to the FFDCAs as well as civil money penalties for violating tobacco product requirements (up to \$1 million for a single violation and up to \$10 million for repeated violations), certain guidances and effective dates, and penalties for retailers (\$250 up to \$10,000). The package label requirements and advertising requirements generally are effective 12-15 months after enactment.

Section 104. Study on raising the minimum age to purchase tobacco products

Within five years after enactment, the secretary of health

and human services will issue a report for a study conducted by an expert panel to consider raising the minimum age to purchase tobacco products.

Section 105. Enforcement action plan for advertising and promotion restrictions

Within six months after enactment, the FDA is directed to develop an action plan to enforce its new regulatory authorities regarding the promotion of cigarettes to youths.

Section 106. Studies of progress and effectiveness

Three years after enactment and every two years thereafter, the FDA must issue a report describing its accomplishments under the tobacco act and impediments to implementing its new regulatory authorities. Within five years after enactment, the Government Accounting Office will issue a study concerning the adequacy of the FDA's resources and authority to implement the tobacco act.

Title II—Tobacco Product Warnings; Constituent and Smoke Constituent Disclosure

The provisions under this title amend the Federal Cigarette Labeling and Advertising Act and do not modify the FFDCAs.

Title III—Prevention of Illicit Trade in Tobacco Products

Section 301. Labeling, recordkeeping, records inspection

One year after enactment, all tobacco products (excluding cigarettes) must bear the statement "sale only allowed in the United States," and the same statement must be included on cigarettes 15 months after the issuance of new regulations now included in the Federal Cigarette Labeling and Advertising Act (Title II of the Family Smoking Prevention and Tobacco Act).

The FDA shall create regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports or imports products, but such records do not extend to individual purchases. The FDA may inspect such records. The FDA will also require manufacturers and distributors of tobacco products to report any knowledge of illegal transactions including the import, export, distribution or offer for sale in interstate commerce without paying duties or taxes as required, or possible illicit marketing.

Section 302. Study and report

Within 18 months after enactment, the Comptroller General of the United States will submit a report to committees in the House and Senate on the cross-border trade in tobacco products including data on its health effects, focusing on minors.

TR

Brian J. Malkin is a partner in the New York office of Frommer Lawrence & Haug LLP. His practice areas include litigation and strategy related to patent validity and infringement, as well as food and drug law. Prior to joining Frommer Lawrence & Haug, Malkin worked as a regulatory counsel at the U.S. Food and Drug Administration in the Center for Drug Evaluation and Research and the Office of the Commissioner.