WASHINGTON — The Food and Drug Administration issued a sweeping set of tobacco rules Thursday that would regulate electronic cigarettes, cigars, and other products for the first time, despite furious resistance from industry groups that say the new rules would be costly and unnecessary.

The 499-page final rule would require regulatory reviews for electronic cigarettes, cigars, and other products that went on sale after Feb. 15, 2007, unless the manufacturers can prove to the FDA that they’re “substantially equivalent” to products that were already being sold or that there is some other reason they should be exempt.

The long-awaited rule would also ban the sale of e-cigarettes to anyone under age 18. Some states have already banned sales to minors, but others have not.

“Today’s rule is a milestone in consumer protection. It marks a new chapter in our efforts to do everything we can under the law to protect Americans from the dangers of tobacco products,” Dr. Robert Califf, the new FDA commissioner, said on a conference call with reporters.
Anti-tobacco groups praised the rule as a major step forward, but e-cigarette advocates said the rule actually got tougher since the original proposal was released two years ago — and warned that it could lead to the end of small businesses across the country that make the products.

“This is a big win for America’s favorite cigarette companies. … It is a giant loss for thousands of small businesses,” said Gregory Conley, president of the American Vaping Association, the main advocacy group for e-cigarette makers. In two to three years, he warned, “nearly every vape shop in the country will be closed.”

There’s likely to be pushback from Republicans on Capitol Hill, too. Representative Tom Cole of Oklahoma, the chairman of the House subcommittee that funds health programs, said the rule was “just another example of the Obama administration’s regulatory overreach and nanny-state mentality.” He’s pushing for legislation to relax the review process for products already on the market.

Congressional Democrats, however, praised the new regulation. Senator Edward Markey of Massachusetts, who noted that his father died of lung cancer, said it was “about time we close this e-cigarette loophole and put in place rules so that Big Tobacco and other companies can no longer develop, market, and sell these products without federal oversight.”

And public health groups declared victory, even though they said they’d still like to see tougher actions, particularly with regard to flavored e-cigarettes.

“This is a critical first step, but it’s only a first step. It took far too long to get here,” said Matt Myers, president of the Campaign for Tobacco-Free Kids.

Robin Koval, chief executive officer of the Truth Initiative, another anti-tobacco group, said she was glad there will now be “a pathway for businesses that can prove their products are safe … versus the Wild West that we’ve had.”
E-cigarettes widely seen as harmful in STAT-Harvard poll. In April 2014, the agency put out its first proposal for the “deeming rule,” which called for extending FDA authority to electronic cigarettes, cigars, pipe tobacco, and other tobacco products. It drew 135,000 comments at the time, forcing the agency to include lengthy responses in the final rule.

Under the regulation released Thursday, manufacturers will have two to three years to come into compliance.

They will have a year, 18 months, or two years to prepare their applications — depending on whether they’re submitting to the reviews or arguing they should be exempt — and another year to win approval from the FDA. The process, known as “premarket review,” is used by the FDA to determine whether potentially risky products are safe.

The rule wouldn’t ban flavored tobacco products, including e-cigarettes. But the agency says it’s working on a proposed rule that would stop cigar companies from using flavors in their marketing, just as cigarette makers aren’t allowed to include flavors in their sales pitches.

The American Vaping Association’s Conley, however, said the final rule shows that e-cigarette makers will have to spend much more time going through the regulatory reviews than the FDA previously acknowledged.

The original proposal said it would take manufacturers an average of 500 hours to prepare their applications for the reviews, but the industry always suspected the FDA was low-balling that estimate, Conley said. Sure enough, the final rule now says it could take an average of 1,500 hours to complete an application — a process he said could cost businesses at least $1 million, and possibly more.

Mitch Zeller, director of the FDA’s Center for Tobacco Products, said the agency estimated the applications could cost “several hundred thousand dollars” at first, but that the process would become cheaper and more efficient over time. For example, he said, the makers of flavored nicotine might be able to open up a “master file” at the FDA with details on their chemical composition, so e-cigarette makers that use them can just refer to the file.

“We think that over time, there’s going to be a lot of efficiency in the review of these applications,” he told reporters.

The rule says the other path — showing that their products are substantially equivalent to others already on the market — “will take considerably less time and money.”

The safety of e-cigarettes has been a topic of heated debate. Manufacturers insist they’re safer than tobacco cigarettes and are an effective way to help people stop smoking, but public health groups insist they’re still dangerous and need to be regulated.

FDA officials said they tried to balance the potential benefits and harmful effects. Zeller said there have been “anecdotal reports” that some people have been able to use e-cigarettes to stop smoking, but he said
the agency still needs more data on what’s happening, including how many people who use e-cigarettes never used tobacco products before.

In any case, he said, “I hope everyone can agree that kids should not initiate on e-cigarettes simply because of the harm that can come from nicotine.”

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The new policy was a long time coming. In 2009, Congress authorized the FDA to regulate additional tobacco products, besides cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

The agency had sent the final version of the rule to the White House Office of Management and Budget for review in October. That set off a round of lobbying by consumer advocates and the cigar industry as well as the nascent e-cigarette or “vaping” companies.

At the same time, uncertain about which way the rule would go, lobbyists for the cigar and e-cigarette industries pushed Congress to create bills that would exempt them from the new rules, or at least “grandfather” in products that are already on the market.

Cole, the House subcommittee chairman, added a measure to the FDA’s funding bill for next year that would soften the regulatory reviews by getting rid of the February 2007 effective date. He said his legislation “provides the same framework for new tobacco products without needlessly subjecting small businesses to unnecessary regulations and without treating law abiding adults like naïve children.”

Zeller, however, said the proposal “would have an enormously adverse impact on public health and the ability of FDA to do its job” — in part by eliminating the reviews of all of the e-cigarette products that came to market after February 2007, but also by clearing the path for future products that are similar in design.

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The rule also brings all kinds of cigars under the FDA’s authority, a step that the cigar lobby had been fighting. There had been a push to exclude so-called “premium” cigars — usually hand-rolled and with more expensive flavorings — but the agency concluded there was no public health justification for excluding any subset of cigars.

One big concern for cigar manufacturers was that cigar boxes, which enthusiasts often regard as works of art, would be subjected to warning labeling requirements. The agency has decided to mandate warning labels on all cigar packages, covering at least 30 percent of the main sections of the package and displayed in at least 12-point font.

The agency did, however, say that it would not require manufacturers to submit their products for approval before reaching the market when some, but not all, blending changes are made, another point of contention from manufacturers.

The rule, which is effective in 90 days, will ban the sale of e-cigarettes and other products to anyone under age 18, either in person or online, and they’ll have to carry warning labels declaring that the products contain nicotine and that nicotine is addictive.

It will also ban the sale of these and other tobacco products in vending machines, and customers will have to show photo identifications to be able to buy them.

Sheila Kaplan contributed to this report.

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