nicopure labs

FDA Deeming Rule and Legal Challenges

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Nothing herein shall be interpreted as legal advice to any party.

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FDA Regulatory Authority

Family Smoking Prevention and Tobacco Control Act (TCA)

Signed into law June 22, 2009

Public Law No. 111-31

- Gave FDA authority to regulate tobacco products under the FDCA "by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products"

What is a Tobacco Product under the TCA?

The term “tobacco product” 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).

(2) The term “tobacco product” does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title.

“**New tobacco Product**”: product introduced or modified after February 15, 2007

All e-cigarettes/vaping products on the US market are new tobacco products and therefore a premarket application must be filed with the FDA

FDA Now Regulates Other Tobacco Products

In 2009 FDA attempted to regulate e-cigarettes as drug/devices, but D.C. Circuit held products made or derived from tobacco must be regulated under Tobacco Control Act unless marketed for therapeutic purposes.

- Sottera, Inc. v. FDA, 627 F.3d 891 (2010)

April 2014 – FDA issued proposed rule (aka "deeming rule")

Comment period

May 10, 2016 – official date of publication of final deeming rule

- Also the date Nicopure Labs challenged the deeming rule in the DC Court

Effective date of the rule : August 8, 2016

- Also date by when all briefs should have been filed in Nicopure Labs litigation

Selected TCA provisions

Premarket Applications for New Tobacco Products

Applies to products introduced or modified after **February 15, 2007**

Must submit application to FDA and receive authorization before marketing

Statute provides **three** premarket review pathways (and one "claim" review pathway – modified risk claim or MRTP)

FDA provides **three deadlines** for newly deemed products

PMTA, Substantial Equivalence and Minor Modification

(1) Section 910(a) requires premarket review and approval of all "new tobacco products,"(***a PMTA application***) unless FDA determines

- (2) that the product is ***substantially equivalent*** to an existing product

OR

- (3) [***minor modification exemption for additives***] the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3)

FDA requires eligible newly deemed products to submit a **minor modification exemption by August 8, 2017** or **a substantial equivalence application by February 8, 2018** – not available to vapor products due to lack of eligible predicates. A "good faith" **PMTA** must be submitted for each SKU by **August 8, 2018**, with addtl. 12 months compliance period.

PMTA content (top line)

Must submit

- full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;
- a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;
- a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;
- an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;
- such samples of such tobacco product and of components thereof as the Secretary may reasonably require;
- specimens of the labeling proposed to be used for such tobacco product; and
- such other information relevant to the subject matter of the application as the Secretary may require.

Consult FDA Guidance Document

To date, FDA has approved 1 PMTA in the 7 years since FDA acquired jurisdiction over tobacco products

Selected FDA Deeming Rule Provisions

Overview

For many provisions, FDA proposes grace periods and extended timelines

Three types of requirements:

1. Immediate (i.e., through 2017)
2. Premarket Tobacco Product Application (Aug 8, 2018)
3. Ongoing and future

Immediate requirements

August 8 - no more changes to the product

- online age verification

- no more modified risk claims (safer than….) and no more marketing claims that the product is “free” of something or has less of something

- no more free samples – arguably only applicable to nicotine containing products

December 31 – File first facility registration, product listing and representative sample of all advertising

(due Dec 31 and June 30 of every year)

February 8 , 2017 – File ingredients list: “a listing of all ingredients, including tobacco, substances, compounds, and additives … brand and by quantity in each brand and subbrand””

- File tobacco documents : “all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives”

Other requirements

May 10, 2018 manufacturing cut-off date: Labeling changes - Nicotine warnings

WARNING: This product contains nicotine. Nicotine is an addictive chemical."

Advertising must bear same warning

May 10, 2018 On packs: The name and place of business • Quantity of the contents • Percentage of domestic and foreign-grown tobacco (*if applicable)* • The statement: "Sale only allowed in the United States" on labels, packaging, and shipping containers of tobacco products

August 8, 2019 – Harmful and Potentially Harmful Constituents (HPHCs)

Ongoing requirements

- FDA can inspect facilities – must ensure good documentation in support of the processes we have, and other customary Quality Assurance practices

- General prohibition against adulteration and misbranding - Creates instances where tobacco products are deemed adulterated or misbranded, such as prepared under insanitary conditions or having false or misleading labeling

Litigation Update

Five lawsuits filed to date

Nicopure Labs v FDA (DC Circuit)

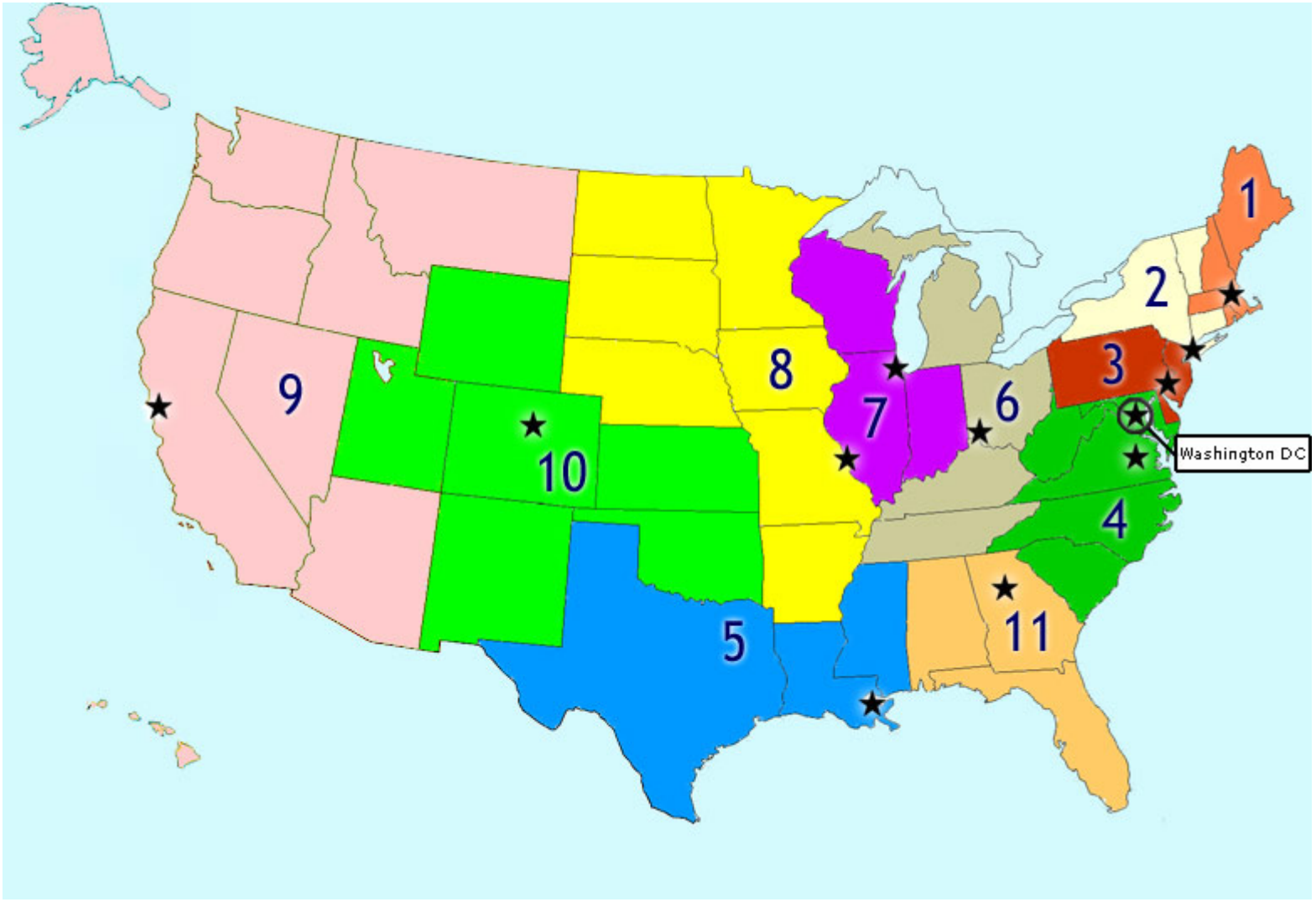
Lost Art Liquids (California)

John Middleton (Altria) – DC Circuit

General Premium Cigar (Florida)

Larry Faircloth (West Virginia)

Map of Federal Court Circuits



Arguments

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Violations of the Administrative Procedure Act

- Includes violations of the First Amendment to the US Constitution (e.g., sampling ban and ban against modified exposure claims)

Other lawsuits also assert APA violations due to Fist and Fifth Amendment violations (taking – e.g., John Middleton)

Violations of the Regulatory Flexibility Act - requires federal agencies to consider the impact of their regulatory proposals on small entities, and, inter alia, to analyze effective alternatives that minimize small entity impacts.

Remedies/Possible Outcomes

- Set aside the entire deeming rule
- Set aside parts of the deeming rule or of the TCA act as applicable to the newly deemed products
- No changes
- Either party may appeal
- If inconsistent outcomes in different circuits an option would be for the Supreme Court to hear those appeals (but Supreme Court does not have to)