Lawsuits Challenging the FDA's Deeming Rule

On May 10, 2016, the U.S. Food and Drug Administration published its final deeming rule, extending the agency's regulatory jurisdiction over tobacco products to e-cigarettes, cigars, hookah, and other products that had not yet been regulated by the FDA. For more information about the FDA's action, see the Consortium's other deeming rule resources. For information on other lawsuits related to FDA tobacco regulation, see our other litigation resources.

Below is an overview of lawsuits challenging the FDA's deeming rule that briefly summarizes the plaintiff's arguments. The FDA's actions are governed by the Administrative Procedure Act (APA)[1] and the Regulatory Flexibility Act (RFA) and so a reviewing court can overturn an agency action if it violates one of these laws.

After the change in administration in January 2017, the government sought extensions of deadlines "to allow new leadership personnel at the Department of Health and Human Services to more fully consider the issues raised" in the lawsuits. On May 1, 2017, the FDA extended all future enforcement deadlines for portions of the deeming rule that have not yet been enforced. In addition, on July 28, 2017, the FDA announced a new regulatory plan that included extending deadlines for premarket review to 2021 and 2022. Following this change, several plaintiffs agreed to suspend their lawsuits.

Nicopure Labs, LLC et al. v. U.S. Food and Drug Administration

No. 1:16-cv-878 (D.D.C. 2016)
No. 17-05196 (D.C. Cir. 2017)

On May 10, 2016, Nicopure Labs, a Florida manufacturer of e-cigarette devices and liquid nicotine, filed suit in the District Court of the District of Columbia, requesting that the court permanently strike down the rule and in the meantime, enjoin enforcement of the rule while the litigation proceeds. Six weeks later, on June 20, 2016, eleven e-cigarette trade groups, Right To Be Smoke-Free (RSF), American E-Liquid Manufacturing Standards Association, American Vaping Association, Electronic Vaping Coalition of America, Georgia Smoke Free Association, Kentucky Vaping Retailers Association, Inc., Louisiana Vaping Association, Maryland Vape Professionals, LLC, New Jersey Vapor Retailers Coalition, Ohio Vapor Trade Association, and Tennessee Smoke Free Association (collectively the RSF Plaintiffs), also filed suit in the District Court of the District of Columbia, requesting that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule.

In an effort by the court to streamline proceedings, these two lawsuits were consolidated because they were based on the same agency action, had the same defendant, and raised some of the same claims. Nicopure filed a motion for summary judgment[2] on July 8, 2016. The RSF Plaintiffs filed their own motion for summary judgment related to unique claims on July 25, 2016. The FDA filed a cross-motion for summary judgment on August 17, 2016 and public health groups filed a supporting *amicus curiae* brief on August 19, 2016. The plaintiffs' consolidated reply was filed on August 26, 2016. The FDA's reply was filed on September 9, 2016, and a hearing on the motions was held on October 11, 2016.

Nicopure's complaint alleged that:

1) the FDA's interpretation of the term, "tobacco product" was "not in accordance with the law" and was "in excess of statutory jurisdiction," a violation of the APA;
2) the enforcement of premarket review against e-cigarette companies would be costly and stifle innovation, rendering the FDA's action "arbitrary and capricious," a violation of the APA;
3) the FDA's cost-benefit analysis for the rule overstated the benefits and understated the costs, an action that was "without observance of procedure required by law," a violation of the APA; and
4) e-cigarette manufacturers would be prohibited from making truthful and non-misleading statements and other forms of protected expression, an action that was "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.

RSF Plaintiffs' complaint alleges that:

1) the FDA's refusal to select a new grandfather date, later than February 15, 2007 for e-cigarettes rendered the Substantial Equivalence premarket review pathway inaccessible, an action that was "arbitrary and capricious," a violation of the APA;
2) the FDA's imposition of the rigorous Premarket Tobacco Product Application process was too expensive and difficult, an action that is a violation of the APA;[3]
3) the FDA's treatment of e-cigarettes in a way that is similar to combustible cigarettes violated the equal protection clause of the Fourteenth Amendment by way of the due process clause in the Fifth Amendment.
4) the FDA has prohibited the distribution of free samples, an action that was "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.
5) e-cigarette manufacturers would be prohibited from making truthful and non-misleading statements, an action that was "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.
6) the FDA's interpretation of the term, "tobacco product" was "unreasonable and unlawful under the APA;"[4]
7) the FDA's Final Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
8) the FDA's cost-benefit analysis for the rule overstated the benefits and understated the costs, an action that is a violation of the APA.[5]

On July 21, 2017, the court granted the FDA's motion for summary judgment, finding that the promulgation of the deeming rule did not violate the APA and that the rule did not infringe on any of the plaintiffs' constitutional rights. The plaintiffs' motion for summary judgment was dismissed. The plaintiffs filed an appeal to the Court of Appeals for the D.C. Circuit.

On September 8, 2017, the American Academy of Pediatrics, the American Lung Association, the American Heart Association, the American Cancer Society Cancer Action Network, the Campaign for Tobacco-Free Kids, and the Truth Initiative filed a motion to intervene as defendants to ensure that the deeming rule is adequately defended, after the government had filed several requests to delay motions in this and other cases, as well as delaying some of the enforcement dates implementing the deeming rule. The plaintiffs and the defendant filed responses to this motion on September 28, 2017, and the potential intervenors filed their reply on October 5, 2017. On March 30, the potential intervenors filed a motion to withdraw their motion to intervene and participate as *amicus curiae*.[6]

The appellants' brief was filed on February 12, 2018. The FDA filed its brief on May 2, 2018. Four *amicus curiae* briefs in support of the FDA were filed on May 9, 2018. The appellants' reply was filed on May 16, 2018, and final briefs were filed on June 6, 2018. Oral arguments are scheduled for September 11, 2018.

Lost Art Liquids, LLC v. U.S. Food and Drug Administration

No. 2:16-cv-3468 (C.D. Cal. 2016)

On May 19, 2016, Lost Art Liquids, a California manufacturer of e-cigarette devices and liquid nicotine, filed suit in the District Court of the Central District of California. Lost Art Liquids has requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA answered the complaint on November 14, 2016.[7]

After several delays to the court's proposed briefing schedule, on November 13, 2017, the plaintiffs filed a motion seeking to compel the FDA to produce the administrative record without a protective order. On November 20, 2017, the FDA filed a memorandum in opposition to the plaintiffs' motion and a hearing on that motion was held on December 12, 2017. On February 6, 2018 the court issued a protective order governing the disclosure of the administrative record. On February 21, 2018 the plaintiffs filed an objection to the protective order.

The lawsuit alleges that:

1) the FDA's Final Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
2) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA;
3) the rule's prohibition on using modified risk descriptors and the requirement that products bear warning labels violate the First Amendment's protection of free speech and the Fifth Amendment's protection from unlawful governmental takings; and

4) the FDA's enforcement of premarket review against e-cigarette companies will be costly, an "abuse of discretion," in violation of the APA.

Enrique Fernando Sanchez Icaza and Global Premium Cigars, LLC v. U.S. Food and Drug Administration

No. 1:16-cv-21967 (S.D. Fla. 2016)

On June 1, 2016, Global Premium Cigars, LLC, a Florida manufacturer of cigars, and its proprietor Enrique Fernando Sanchez Icaza, filed suit in the District Court of the Southern District of Florida. The plaintiffs have requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on October 3, 2016.[8]

The lawsuit alleged that:

1) the FDA's Initial Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
2) the enforcement of premarket review against cigar companies will be costly and there is no evidence to support the requirement that cigar boxes carry a warning label covering 30% of the principal display panel, actions that are "arbitrary and capricious," violations of the APA;
3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA;
4) the required warning labels and the enforcement of premarket review with respect to labeling violate the First Amendment's protection of free speech;
5) the implementation of required warning labels on cigar boxes amounts to a taking, a violation of the Fifth Amendment's protection from unlawful governmental takings; and
6) the enforcement of premarket review with respect to all products marketed after February 15, 2007, violates the due process clause of the Fifth Amendment.

On July 31,2017, the court granted a joint motion to stay the proceedings because the FDA's newly announced regulatory plan for tobacco products "affords Plaintiffs much of the relief they seek." The case may be reopened by a motion by one of the parties.

Larry W. Faircloth v. U.S. Food and Drug Administration

No. 2:16-cv-5267 (S.D. W.V. 2016)

On June 10, 2016, Larry W. Faircloth, a user of e-cigarette devices and liquid nicotine, filed suit in the District Court of the Southern District of West Virginia. Faircloth has requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. In lieu of answering the complaint, the FDA filed a motion to dismiss the case on October 28, 2016.[9] Faircloth filed a response to this motion on November 30, 2016, and the FDA filed a reply to plaintiff's response on December 12, 2016.

On September 28, 2017, the court granted the motion to dismiss as to all claims but one. On the remaining claim, that the deeming rule violates the first amendment, the FDA filed its answer on October 12, 2017.

The lawsuit alleges that:

1) the FDA's interpretation of the term, "tobacco product" is "not in accordance with the law" and "in excess of statutory jurisdiction," a violation of the APA;
2) the enforcement of premarket review against e-cigarette will drive up the costs for devices and liquids for consumers and push consumers toward cigarettes, rendering the FDA's action "arbitrary and capricious," a violation of the APA;
3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, an action that is "without observance of procedure required by law," a violation of the APA;
4) the rule will prevent consumers from receiving truthful and non-misleading statements and other forms of protected expression, such as free samples of products, an action that is "contrary to [the] constitutional right," of free speech protected by the First Amendment, in violation of the APA; and
5) by removing many e-cigarettes from the market, the FDA has prevented the state of West Virginia from reducing its Medicaid costs by promoting e-cigarettes over combustible tobacco products to reduce healthcare costs, depriving the state of its sovereignty, in violation of the Tenth Amendment's protection of federalism.

Cyclops Vapor 2, et al. v. U.S. Food and Drug Administration

No. 2:16-cv-556 (M.D. Ala. 2016)

On July 8, 2016, Cyclops Vapor 2, LLC, Tiger Vapor, LLC, and Karma S Clouds, LLC, Alabama-based manufacturers and distributors of e-cigarette devices and liquid nicotine, filed suit in the Middle District of Alabama. The plaintiffs have requested that the court permanently strike down the rule. The FDA filed its answer on November 28, 2016.[10] The plaintiffs filed a motion for summary judgment on February 1, 2017.

The lawsuit alleges that:

1) the FDA's interpretation of the term, "tobacco product" is "in excess of statutory jurisdiction," a violation of the APA;
2) the enforcement of premarket review against e-cigarette companies will be costly, stifle innovation, and does not account for the possibility that e-cigarettes are less harmful than combustible cigarettes, rendering the FDA's action "arbitrary and capricious," a violation of the APA;
3) the FDA's cost-benefit analysis for the rule overstates the benefits and understates the costs, a violation of the APA[11] and the RFA; and
4) e-cigarette manufacturers will be prohibited from making truthful and non-misleading statements and other forms of protected expression, including distributing free samples, an action that is "contrary to [the] constitutional right" to free speech protected by the First Amendment, a violation of the APA.

On July 24, 2017, the American Academy of Pediatrics, the American Lung Association, the American Heart Association, the American Cancer Society Cancer Action Network, the Campaign for Tobacco-Free Kids, and the Truth Initiative filed a motion to intervene as defendants to ensure that the deeming rule is adequately defended, after the government had filed several requests to delay motions in this and other cases, as well as delaying some of the enforcement dates implementing the deeming rule. The parties filed responses to this motion on August 10, 2017, and the potential intervenors filed their reply on August 18, 2017.

On July 31, the parties filed a joint motion to stay the proceedings because the FDA's newly announced regulatory plan for tobacco products "affords Plaintiffs much of the relief they seek." If granted the motion would administratively close the case but it could be reopened by a motion of one of the parties.

On August 10, 2017, the court held a hearing on both the motion to intervene and the motion to stay the proceedings. On March 22, 2018, the court granted the public health groups' motion to intervene and also granted the motion to stay the case pending the outcome of *NicoPure Labs LLC et al. v. FDA.*

Cigar Association of America et al. v. U.S. Food and Drug Administration

No. 1:16-cv-1460 (D.D.C.)
No. 18-05195 (D.C. Cir. 2018)

On July 15, 2016, the Cigar Association of America, the International Premium Cigar and Pipe Retailers Association, and Cigar Rights of American, non-profit trade associations for retailers and manufacturers, filed suit in the District Court of the District of Columbia. The plaintiffs requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on October 26, 2016.[12] The plaintiffs filed a motion for summary judgment on February 13, 2017.

The lawsuit alleges that:

1) the enforcement of premarket review will be costly, rendering the FDA's action "arbitrary and capricious" in violation of the APA;
2) the imposition of user fees is an illegal tax, an action that is in excess of statutory authority and therefore a violation of the APA;
3) the imposition of user fees on cigar manufacturers but not e-cigarette manufacturers is "contrary to [the] constitutional right" to due process protected by the Fifth Amendment, a violation of the APA;
4) the FDA's Final Regulatory Flexibility Analysis did not properly quantify the costs of the rule or identify significantly less costly alternatives to the rule, a violation of the RFA;
5) the FDA's decision to regulate all cigars rather than exempting premium cigars is an action that is "arbitrary and capricious" in violation of the APA;
6) the FDA's imposition of particularly sized warning labels without adequately explaining why it decided on the size and format is "arbitrary and capricious" in violation of the APA;

7) the required warning labels impermissibly restrict speech, a violation the First Amendment;
8) the FDA's decision to treat retailers who blend or repackage pipe tobacco or cigars as manufacturers is "arbitrary and capricious" in violation of the APA;
9) the FDA's decision to regulate pipes as components or parts of a tobacco product is "arbitrary and capricious" in violation of the APA.

On July 24, 2017, the American Academy of Pediatrics, the American Lung Association, the American Heart Association, the American Cancer Society Cancer Action Network, the Campaign for Tobacco-Free Kids, and the Truth Initiative filed a motion to intervene as defendants to ensure that the deeming rule is adequately defended, after the government had filed several requests to delay motions in this and other cases, as well as delaying some of the enforcement dates implementing the deeming rule. The plaintiffs and the defendant filed responses to this motion on August 7, 2017, and the potential intervenors filed their reply on August 14, 2017. The court has asked for supplemental briefs from the parties and potential intervenors to be filed on September 20, 2017. On October 14, 2017, the court denied the motion to intervene.

Following the FDA's July announcement of a new regulatory plan, the plaintiffs agreed to narrow the scope of their lawsuit and the court established a new briefing schedule. The plaintiffs filed a motion for summary judgment on October 3, 2017. The FDA filed its opposition to the plaintiffs' motion and its own motion for summary judgment by October 24, 2017 and public health groups filed a supporting *amicus curiae* brief on October 31, 2017. The plaintiffs filed their reply on November 14, 2017. The FDA filed its reply on December 4, 2017 and oral arguments were heard on December 14, 2017.

On May 15, 2018, the court partially granted and partially denied the plaintiffs' motion for summary judgment. The court found that the required warning labels did not violate the First Amendment, that the FDA's user fee rule was legal, and that the FDA's decision to regulate pipes did not violate the APA. The court did find that the FDA's regulation of tobacco retailers who blend pipe tobacco as manufacturers was a violation of the APA and remanded the issue to the FDA. The plaintiffs filed an appeal to the Court of Appeals for the D.C. Circuit.

On June 8, 2018, the plaintiffs filed a motion for an injunction of the enforcement of the warning label requirement for cigars and pipe tobacco pending the resolution of the plaintiffs' appeal. On June 22, 2018, the FDA filed its memorandum in opposition to the plaintiffs' motion and on June 29, 2018, the plaintiffs filed their reply regarding the motion to for an injunction. On July 5, 2018, the court granted the injunction, staying enforcement of the warning label requirement for cigars and pipe tobacco until sixty days after the resolution of the plaintiffs' appeal.

Appellant and appellee procedural motions are due by July 30, 2018 and dispositive motions are due by August 13, 2018.

En Fuego Tobacco Shop LLC, et al. v. U.S. Food and Drug Administration

No. 4:18-cv-00028 (E.D. Tex.)

On January 11, 2018, En Fuego Tobacco Shop LLC, Cuba Libre Enterprises LLC, and the Texas Cigar Merchants Association, a cigar retailer, a manufacturer, and a trade association, filed suit in the Eastern District of Texas. The plaintiffs requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA's filed its answer on March 19, 2018 along with a motion to transfer the venue to the U.S. District Court for the District of Columbia. The motion to transfer highlights the fact that the plaintiffs in this litigation are a member of one of the organizations that is a plaintiff in *Cigar Association of America, et al. v. FDA*, the attorneys representing the plaintiffs in this lawsuit also represent the plaintiffs in that case, and that the claims made in this case are identical to the claims in that case. The transfer of venue would allow this case to be consolidated with *Cigar Association of America*. The plaintiffs filed a response in opposition to the motion to transfer on April 2, 2018. The FDA filed a reply on April 9, 2018. The plaintiffs filed a sur-reply on April 16, 2018.

On March 27, 2018, the plaintiffs amended their complaint and filed a motion for summary judgment which the court deemed filed on April 10, 2018. On April 16, 2018, the FDA filed a motion to stay briefing on the plaintiff's motion for summary judgment pending the outcome of the FDA's motion to transfer. On April 20, 2018, the court stayed the briefing on the plaintiff's motion for summary judgment until the court ruled on the FDA's motion to stay. The plaintiffs filed their response to the motion to stay on April 30, 2018. On May 22, 2018, the court denied the FDA's motion to transfer and denied the FDA's motion to stay briefing. On June 5, 2018, the FDA filed an appeal of the court's denial of the agency's motion to transfer and the plaintiffs filed their response to the FDA's appeal on June 12, 2018.

While the appeal of the denial of the motion to transfer was pending, briefing continued on the plaintiffs' motion for summary judgment. The FDA filed its response to the plaintiffs' motion for summary judgment on June 19, 2018 and the plaintiffs filed their reply on June 22, 2018. A hearing on the motion was held on June 26, 2018.

On July 2, 2018, the court granted the FDA's motion to transfer, overturning its previous decision to deny the motion. On July 5, 2018, the plaintiffs filed an appeal of that order and the FDA filed its response to the appeal on July 17, 2018.

The lawsuit alleges that:

1) the required warning labels impermissibly restrict speech, a violation the First Amendment;
2) the required warning labels unconstitutionally compel speech, a violation of the First Amendment;
3) the required submission of warning plans is an unconstitutional prior restraint and unconstitutionally restricts speech, a violation of the First Amendment;
4) the FDA did not make findings required by the Tobacco Control Act before imposing required warning labels;[13]

5) the FDA did not make findings required by the Tobacco Control Act before imposing required warning labels, a violation of the APA.

Moose Jooce, et al. v. Gottlieb

No. 1:18-cv-00203 (D.D.C.)

On January 30, 2018, Moose Jooce, Mountain Vapors, Rustic Vapors, and Dutchman Vapors, e-cigarette manufacturers and retailers, filed suit in the District Court of the District of Columbia. The plaintiffs requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on April 2, 2018 along with a notice informing the court that it was seeking to transfer *Rave Salon* and *Hoban* to the District of Columbia so that the three cases could be consolidated. On July 17, 2018, the court ordered that the proceedings in this case be stayed until the expiration of the transfer order in *Hoban*.

The lawsuit alleges that:

1) the FDA employee whose name appears in the Federal Register notice for the deeming regulation is not a principal officer or inferior officer, a violation of the Appointments Clause of the Constitution;
2) the prohibition on making unauthorized modified risk claims unconstitutionally restricts speech, a violation of the First Amendment.

Rave Salon Inc., et al. v. Gottlieb

No. 3:18-cv-00237 (N.D. Tex.)
No. 1:18-cv-01615 (D.D.C.)

On January 30, 2018, Rave Salon, Inc., an e-cigarette manufacturer and retailer, filed suit in the Northern District of Texas. The plaintiffs requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on April 27, 2018 along with a motion to transfer the litigation to the District of Columbia where an identical case had been filed by the same attorneys representing different parties. The plaintiffs filed their response to the motion on May 18, 2018 and the FDA filed its reply on June 1, 2018. On June 4, 2018, the court granted the motion to transfer. On June 8, 2018, the plaintiffs filed a motion to stay the court's order which the court denied on June 11, 2018. The case was transferred to the District of Columbia on July 6, 2018.

The lawsuit alleges that:

1) the FDA employee whose name appears in the Federal Register notice for the deeming regulation is not a principal officer or inferior officer, a violation of the Appointments Clause of the Constitution;
2) the prohibition on making unauthorized modified risk claims unconstitutionally restricts speech, a violation of the First Amendment.

Hoban, et al. v. U.S. Food and Drug Administration

No. 0:18-cv-00269 (D. Minn.)

On January 30, 2018, Jen Hoban, The Plume Room LLC, J.H.T. Vape LLC, Lakes Vape Supply, LLC, and Tobacco Harm Reduction 4 Life, e-cigarette manufacturers and retailers, filed suit in the District of Minnesota. The plaintiffs requested that the court issue a preliminary injunction barring enforcement of the rule while the litigation proceeds and asked the court to permanently strike down the rule. The FDA filed its answer on April 13, 2018 along with a motion to transfer the litigation to the District of Columbia where an identical case had been filed by the same attorneys representing different parties. The plaintiffs responded to the motion on May 4, 2018. The FDA filed its reply on May 18, 2018. On June 26, 2018, the court granted the motion to stay. On June 27, 2018, the plaintiffs filed a motion to stay the transfer order until plaintiffs filed an appeal of the decision. On July 5, 2018, the FDA filed its response to the plaintiffs motion and on July 6, 2018, the court granted the motion, staying the order until July 26, 2018.

The lawsuit alleges that:

1) the FDA employee whose name appears in the Federal Register notice for the deeming regulation is not a principal officer or inferior officer, a violation of the Appointments Clause of the Constitution;
2) the prohibition on making unauthorized modified risk claims unconstitutionally restricts speech, a violation of the First Amendment.

In addition to these cases, John Middleton Co. LLC, a subsidiary of Altria Group, Inc. (formerly Philip Morris Companies) that manufactures cigars and pipe tobacco, filed suit in the District Court of the District of Columbia, challenging the enforcement of the prohibition on the use of modified risk descriptors against its brand, Black & Mild. On July 15, 2016 in light of the FDA's position that it did not intend to enforce that prohibition against Black & Mild, John Middleton voluntarily dismissed its lawsuit, without prejudice, allowing the company to refile its lawsuit in the future.

Other Resources

For more information on the FDA's regulation of tobacco products, visit our FDA Tobacco Action Center.

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[1] The APA provides a list of causes of action that allow a reviewing court to set aside an agency action. Plaintiffs often list the relevant section entirely or multiple sections as the causes of action have a degree of overlap. There are four causes of action relevant to FDA tobacco regulation. A court may overturn a rule if it finds that it is: 1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law; 2) contrary to constitutional right, power, privilege, or immunity; 3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or 4) without observance of procedure required by law.

[2] A motion for summary judgment asks a court to decide a case on the law when there are no facts in dispute.

[3] The complaint fails to identify a particular section of the APA that has been violated and thus there is no reference to statutory language.

[4] "Unreasonable and unlawful" is not a cause of action under the APA. The complaint does not reference APA statutory language.

[5] The complaint fails to identify a particular section of the APA that has been violated and thus there is no reference to statutory language.
[6] On March 27, 2018, the organizations that had filed the motion to intervene filed a lawsuit challenging the FDA's delay in implementing the premarket review requirements for products covered by the deeming regulation.
[7] The significant delay between the filing of the complaint and the due date for the government's answer is due to the fact that the government was not properly served with the lawsuit until September 15, 2016.
[8] The significant delay between the filing of the complaint and the filing of the government's answer is due to the fact that the government was not properly served with the lawsuit until August 4, 2016.
[9] Raising a defense such as a lack of standing to challenge the regulation, as the FDA as done here, must be done by motion before an answer is filed. Fed.R.Civ.P. 12(b). If the court denies this motion, the FDA has 14 days to answer the complaint. Fed.R.Civ.P. 12(a)(4).
[10] The significant delay between the filing of the complaint and the due date for the government's answer is due to the fact that the government was not properly served with the lawsuit until September 29, 2016.
[11] The complaint fails to identify a particular section of the APA that has been violated and thus there is no reference to statutory language.
[12] The significant delay between the filing of the complaint and the due date for the government's answer is due to the fact that the government was not properly served with the lawsuit until August 29, 2016.
[13] The complaint only identifies the Tobacco Control Act as the source of law for this cause of action and thus there is no reference to the APA or a constitutional provision that has been violated.