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Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION TO STAY AND FOR RECONSIDERATION

On behalf of the National Association of Convenience Stores ("NACS")[1] and the National Grocers Association ("NGA")[2] (collectively, "Petitioners"), we respectfully submit this

[1] NACS is an international trade association representing the convenience store industry with more than 2,200 retail and 1,800 supplier companies as members, the majority of whom are based in the United States. The convenience store industry as a whole operates approximately 154,000 stores across the United States. In 2015, the industry employed more than two and a half million workers and generated $574.8 billion in total sales, representing approximately 3.2 percent of the U.S. GDP. In light of the number of fuel and other transactions in which our industry engages, we handle approximately one of every 30 dollars spent in the United States. Our retailers serve about 160 million people per day – around half of the U.S. population – and our industry processes over 73 billion payment transactions per year. Approximately 63 percent of convenience store owners operate a single store, and approximately 75 percent of the industry is composed of companies that operate ten stores or fewer.

[2] NGA is the national trade association representing supermarkets, from single store operators to regional chains, that comprise the independent channel of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating a variety of formats. Most independent operators are serviced by wholesale distributors, while others may be partially or fully self-distributing. Some independents are publicly traded, but with controlling shares held by the family and others are employee owned. Independents are the true "entrepreneurs" of the grocery industry and dedicated to their customers, associates, and communities. The independent supermarket channel is accountable

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petition under 10 C.F.R. §§ 10.25, 10.30, 10.33, and 10.35 to request the Commissioner of Food and Drugs to stay and reconsider the Final Rule on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (the "Final Rule").[3]

I. Decision Involved

Petitioners respectfully request that the Commissioner stay and reconsider the Final Rule on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.[4]

II. Actions Requested

A. Pursuant to 21 C.F.R. § 10.35(b), Petitioners request that the Commissioner of Food and Drugs (the "Commissioner") stay the effective date of the Final Rule pending reconsideration of its merits, which would be in the public interest.[5]

B. Pursuant to 21 C.F.R. §§ 10.25(a)(2) and 10.33(b), Petitioners respectfully request that the Commissioner reconsider the Final Rule and direct FDA staff to commence a new rulemaking governing the implementation of section 4205 of the Patient Protection and Affordable Care Act, 21 U.S.C. § 343(q)(5)(H).[6]

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for close to one percent of the nation's overall economy and is responsible for generating $131 billion in sales, 944,000 jobs, $30 billion in wages, and $27 billion in taxes.

[3] Food Labeling, 21 C.F.R. Part 101 (2014); Final Rule, Dept. of Health and Human Services, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines*, 79 Fed. Reg. 71156 (Dec. 1, 2014) (hereinafter "Final Rule).

[4] *Id.*

[5] Petitioners acknowledge that a stay of the Final Rule's effective date may trigger obligations under the Administrative Procedures Act, 5 U.S.C. § 550, *et seq.* For reasons set forth below, however, FDA has good cause to issue an immediate stay pending reconsideration of the Final Rule's merits (for which it may and should invite further public comment), due to the impossibility of implementation under current regulatory text and guidance, and serious legal questions presented by the Final Rule. *See* 5 U.S.C. § 553(b)(B) (advance public notice and opportunity for comment not required when the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest).

[6] Petitioners recognize that this request for a stay of the effective date and reconsideration of the Final Rule is not timely because more than 30 days have lapsed since publication of the Final Rule. Petitioners request, however, that the Commissioner exercise discretion to permit

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III. Statement of Grounds

A. Background

This Petition arises out of the long, tangled history of the menu labeling provisions of the Patient Protection and Affordable Care Act ("ACA"). Enacted on March 23, 2010, those statutory provisions are now expected to take regulatory effect on May 5, 2017. The seven-year delay in the regulatory implementation of section 4205 is a testament to how unworkable the underlying statute is – a situation only exacerbated by the FDA's Final Rule.

NACS, NGA and many similarly situated parties sought common sense implementation of section 4205 after its enactment.[7] Unfortunately, the Final Rule largely ignored the myriad real-world complications of implementing the underlying statute. Foremost, FDA failed to properly consider the *dis*similarity between restaurants and other retail businesses, and whether non-restaurant businesses should be covered by the rule at all. Several related problems under the Final Rule followed, including lack of flexibility for different business models with respect to how and where calorie counts are displayed, uncertainty related to key definitions and elements of the Final Rule (e.g., what constitutes a "menu" and natural calorie variations between fresh food products), and harsh penalties for non-compliance—including criminal penalties—that are out of proportion to the prospective violations at issue.

Not surprisingly, the Final Rule has met with stiff resistance. Indeed, Congress itself has delayed implementation of the Final Rule by prohibiting use of any funds to implement,

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this filing for good cause pursuant to 21 C.F.R. §§ 10.33(b) and 10.35(b). Good cause exists here for all of the reasons set forth in this Petition, including the Final Rule's pending effective date and impossibility of compliance under current regulations and guidance.

[7] *See* Letter from Carin Nersesian, Director, Government Relations, NACS to Dr. Margaret Hamburg, Commissioner of Food and Drugs, Food and Drug Administration, Docket ID FDA-2011-F-0172-0468 (July 8, 2011) (commenting on FDA's Proposed Rule on Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19192 (Apr. 6, 2011) (hereinafter "Proposed Rule")); Letter from Thomas F. Wenning, Executive Vice President and General Counsel, NGA to Margaret Hamburg, Commissioner of Food and Drugs, Food and Drug Administration, Docket ID FDA-2011-F-0172-0456 (July 8, 2011) (commenting on FDA's Proposed Rule); *see also* Letter from Erik Lieberman, Regulatory Counsel, Food Marketing Institute to Dr. Margaret Hamburg, Commissioner of Food and Drugs, Food and Drug Administration, Docket ID FDA-2011-F-0172-0455 (July 8, 2011) (commenting on FDA's Proposed Rule); Letter from Lisa Mullings, President and CEO, NATSO to Dr. Margaret Hamburg, Commissioner of Food and Drugs, Food and Drug Administration, Docket ID FDA-2011-F-0172-0467 (July 8, 2011) (commenting on FDA's Proposed Rule).

administer, or enforce it until one year after publication of final guidance by FDA.[8] The U.S. House of Representatives last year also passed legislation, on a broad bipartisan basis, to significantly amend section 4205.[9] Despite the inability of many regulated businesses to comply with the Final Rule, we are now on the verge of those regulations becoming effective and putting thousands of businesses and their employees at substantial risk of liability. Petitioners thus make this filing as a last resort.

B. Argument

Petitioners urge the Commissioner to grant this Petition because:

(1) It is impossible for Petitioners' members and others to comply with the Final Rule and its guidance as they are currently written;
(2) FDA dramatically underestimated the costs of compliance, particularly for non-restaurant retailers;
(3) FDA exceeded its authority under section 4205 of the Affordable Care Act and failed to address material comments relating to the scope of the Final Rule;
(4) The Final Rule restricts commercial speech in violation of the First Amendment; and
(5) Implementation of the Final Rule is inconsistent with the Administration's agenda to alleviate unnecessary regulatory burdens on businesses.

1. Petitioners Now Know that the Final Rule Cannot Be Implemented.

Petitioners have consistently argued that the requirements of the Final Rule (and the proposed rule before it) cannot be implemented.[10] NACS' and NGA's member businesses are

[8] *See* Consolidated Appropriations Act, 2016, Pub. Law 114-113 (Dec. 18, 2015) (prohibiting use of any funds to implement, administer, or enforce the Final Rule until the later of December 1, 2016, or one year after the date on which FDA issued final implementation guidance, which occurred on May 5, 2016).

[9] H.R. 2017, the Common Sense Nutrition Disclosure Act of 2015, passed the House of Representatives on February 2, 2016, by a vote of 266-144. The legislation had 99 cosponsors. Companion legislation was introduced in the Senate (S. 2217). According to the Committee Report, the legislation would amend section 4205 of the Affordable Care Act to "provide a flexible approach to calorie disclosures by allowing for food establishments to provide consumers with caloric information in the most helpful way" in light of "menu labeling regulations that are burdensome and inappropriate for food establishments such as convenience stores, supermarkets, grocery stores and pizza restaurants." Committee Report, House Comm. on Energy and Commerce, Rep. No. 114-413 (Feb. 2, 2016).

[10] *See* NACS and NGA letters cited *supra* note 6; *see also* Letter from Jon Taets, Director, Government Relations, NACS to Tom Price, Secretary of Health and Human Services

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spending tremendous resources trying to implement the Final Rule's requirements, but they do not have a clear picture of what is necessary to comply.

For instance, during a recent education session hosted by FDA on the Final Rule,[11] Petitioners and others requested clarity on some fundamental issues. We asked FDA staff to clarify the distinction between a menu, which requires calorie information, and an advertisement or marketing piece, which does not require calorie information. FDA staff would not (or could not) provide an answer. Instead, they admitted that they had not made determinations on these kinds of very basic compliance questions.

The FDA's unwillingness or inability to specify what constitutes a "menu" is a fundamental bar to compliance (with attendant enforcement risks), and FDA's final guidance does not resolve this issue.[12] The regulation characterizes a "menu" or "menu board" as "the primary writing of the covered establishment from which a customer makes an order selection."[13] Factors for determining whether a writing is a "primary writing" include, *inter alia*: whether it lists the name of a standard menu item or an image of a standard menu item; whether it gives the price of that item; and whether it can be used by a customer to make an order selection at the time the customer views the writing.[14]

(Feb. 24, 2017) (explaining that specific questions regarding Final Rule implementation have not been—or cannot be—answered by FDA officials mere weeks before the effective date); Letter from Thomas Wenning, Executive Vice President and General Counsel, NGA to Andrew Perraut, Policy Analyst, Office of Information and Regulatory Affairs, Office of Management and Budget (Nov. 4, 2011) (reiterating concerns about scope of FDA's Proposed Rule).

[11] FDA Public Workshop to Address Menu Labeling Final Rule, College Park, MD, July 7-8, 2016, notice available at: https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm506247.htm (last visited Mar. 22, 2017).

[12] FDA, *A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11): Guidance for Industry* (April 2016), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM461963.pdf (hereinafter "final guidance").

[13] *Id.* at 8.

[14] *Id.*

Under NACS' members' business model, marketing pieces change periodically and often appear throughout the store, in store windows, on shelves, on sidewalk boards, and on gas pumps to show special food deals—and these pieces regularly include names, images, and prices of standard food items. Further, they are part of broader advertising campaigns, which are planned and created over a period of months. FDA cannot tell us when a customer can make an order selection from an advertisement. Staff has indicated that signs located outside a store might allow this to happen because a customer could remember what was on the sign and then enter the store, but staff has not provided any definitive answer or any reliable way for businesses to make this determination. Many of our members already have produced advertising that will be in their stores in May. Because of the lack of answers from FDA as to which materials are required to have calorie counts, businesses must *guess* at how to comply.

Clarity from FDA also is lacking on how to deal with the natural calorie variations for foods. During a call with FDA staff, for example, we asked how NACS members should provide calorie counts for fried chicken, given that chickens (and their various parts) come in different sizes. The Final Rule does not provide necessary allowances for these variations, and again, FDA staff cannot answer how we should comply with the law just weeks away from the May 5th effective date.

Finally, many businesses do not even know whether they are covered under the Final Rule. FDA's 20-plus location determination for covered businesses is effectively a "same name" test, which has led to some confusion. NGA has asked whether hundreds of independently owned and operated stores that are part of the Independent Grocers Alliance ("IGA") are covered by the Final Rule. IGA's members are independent and family-owned grocery stores that display IGA's label as a symbol of quality, locally-owned establishments. It is not clear, to date, whether the IGA name on these stores renders them subject to the menu labeling requirements because FDA has not responded to NGA's request for clarification. Of course, it is impossible for these stores—should FDA deem them covered—to comply with the Final Rule in the next six weeks.

Clearly, serious compliance and coverage questions remain under the Final Rule, and even if FDA were to address all of them today, there would not be sufficient time for businesses to be in compliance on May 5th. The impossibility of compliance for many businesses is reason enough to stay the Final Rule.

2. FDA Dramatically Underestimated the Cost of Compliance for Non-Restaurant Retailers.

In its final Regulatory Impact Analysis ("RIA"), FDA itself estimated that there would be approximately 298,600 covered establishments, organized under 2,130 chains,[15] and that the

[15] Final Regulatory Impact Analysis, Department of Health and Human Services, Food and Drug Administration, *Food Labeling: Nutrition Labeling of Standard Menu Items in*

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costs of compliance would amount to nearly $1 billion over ten years.[16] These estimates, however, bear absolutely no relation to the real world costs that Petitioners' members are incurring in preparation for the May 5th compliance date.

The supermarket industry alone projects that it will incur *$1 billion* in initial compliance costs.[17] For the convenience store industry, which has more than 150,000 stores, it will cost thousands of dollars per covered store to comply, and overall costs for the industry will run into the hundreds of millions of dollars.

Petitioners encourage FDA to reconsider, along with the substance of the Final Rule, its cost estimates, especially with respect to non-restaurant retail businesses that are facing particularly burdensome compliance challenges.

3. The Final Rule is Inconsistent with the Menu Labeling Statute and FDA Failed to Adequately Consider Comments on the Scope of the Final Rule.

Section 4205 of the Affordable Care Act required FDA to mandate disclosure of certain calorie information by any "restaurant *or similar retail food establishment* that is part of a chain with 20 or more locations doing business under the same name."[18] As noted above, the FDA wildly expanded the scope of "similar retail food establishment" to effectively include any business that sells even a small amount of prepared food. The Final Rule now reaches "bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located in entertainment venues (such as amusement parks, bowling alleys, and movie theaters), food service vendors (e.g., ice cream shops and mall cookie counters), food take-out and delivery establishments (such as pizza take-out and delivery establishments), grocery stores, superstores, quick service restaurants, and table service restaurants."[19]

Restaurants and Similar Retail Food Establishments, Docket No. FDA-2011-F-0172, at 7 (Nov. 2014).

[16] *Id.*

[17] *See* National Grocers Association, Food Marketing Institute, and Food Industry Association Executives, *Day in Washington; Supermarkets Support the Common Sense Nutrition Disclosure Act (H.R. 2017; S. 2217) to Fix FDA Menu Labeling Regulations* (Apr. 19-21, 2016) available at www.fmi.org/docs/default-source/gr/2016-diw-menu-labeling.pdf?sfvrsn=2 (last visited Mar. 22, 17).

[18] 21 U.S.C. § 343(q)(5)(H)(i).

[19] Final Rule, 79 Fed. Reg. 71156, 71157 (Dec. 1, 2014).

Notably, Congress could easily have imposed this mandate on any business that sells prepared food. Congress, however, chose not to do so. Instead, it included key limiting language and required the affected business to be "*similar*" to a restaurant. A considerably more reasonable reading of the statute therefore would limit the menu labeling mandate to businesses whose primary business is the sale of prepared food and thus already distribute or prominently display food menus that can be augmented with calorie information in a cost-effective way that is helpful to customers.

Unlike restaurants and businesses similar to restaurants, the sale of prepared food is *far* from the primary business of NACS' or NGAs' members. In fact, NACS' most recent State of the Industry Report shows that sales of fuel comprised 68.22% of total sales.[20] Food service (prepared foods, commissary/packaged sandwiches, hot dispensed beverages, cold dispensed beverages, and frozen dispensed beverages), on the other hand, only accounted for 6.63% of total sales.[21] The Final Rule commandeers limited display space for the government's message for a very small segment of our members' business. It also imposes tremendous compliance costs on businesses that clearly do not have restaurant-like stores or business models.

Petitioners contend that FDA's vast expansion of the calorie mandate is contrary to the text of the Affordable Care Act and is wholly unreasonable; in fact, it is so arbitrary and capricious that it violates the Administrative Procedures Act.[22] Furthermore, FDA failed to adequately address substantive comments on the proper scope of the Final Rule. In fact, the following issues were raised in a single comment letter[23] and were not adequately addressed by FDA:

- The similarity (or here, dissimilarity) between restaurants and other retail businesses and whether/how those businesses should be covered by menu labeling requirements;
- Confusion regarding what constitutes "prepared food;"
- The need for flexibility regarding sign/calorie information placement to accommodate different business models and retail store dynamics; and
- Impact on small business food suppliers with fewer than 20 locations.

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[20] NACS, *State of the Industry Report* (2015), at 47.

[21] *Id.*

[22] *See* 5 U.S.C. § 706 (establishing scope of review of agency actions).

[23] *See* Letter from Food Marketing Institute commenting on FDA's Proposed Rule *supra* note 6.

Petitioners urge FDA to stay and reconsider the Final Rule in order to properly address these issues, which are fundamental to the current problems that still exist with the regulation, and to ensure that the Final Rule is consistent with the authorizing statute and congressional intent.

4. The Final Rule Presents Serious Issues with Respect to First Amendment Protections for Commercial Speech.

The Supreme Court has a well settled approach to evaluating restrictions on commercial speech under the First Amendment.[24] While the government may prevent the dissemination of commercial speech that is "false, deceptive, or misleading, or that proposes an illegal transaction," commercial speech that does not fall within one of those categories "may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest."[25] With respect to disclosure requirements imposed by the government, the Court has stated in dicta: "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech."[26] Further, it states, an advertiser's[27] First Amendment rights are adequately protected when disclosures are required "*as long as* the disclosure requirements are reasonably related to the State's interest in preventing deception of consumers."[28]

Here, it is unclear how requiring nutrition information prevents deception of consumers. No evidence of which Petitioners are aware suggests that consumers are routinely being misled about the nutritional value of all prepared foods. Further, FDA itself recognizes that the caloric content of prepared foods can vary and calorie labels are not purely factual calculations. In fact,

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[24] *See, e.g., Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 637 (1985) ("There is no longer any room to doubt that what has come to be known as 'commercial speech' is entitled to the protection of the First Amendment . . . . Our general approach to restrictions on commercial speech is also by now well settled.").

[25] *Id.* at 638 (internal citations omitted).

[26] *Id.* at 651.

[27] Some courts limit the reach of *Zauderer* to required disclosures *in advertisements*. *See, e.g., Nat'l Ass'n of Manufacturers v. S.E.C.*, 800 F.3d 518, 523-24 (D.C. Cir. 2015) (holding *Zauderer* does not apply to cases not involving voluntary commercial advertising). *Zauderer*, however, characterizes advertisements broadly as speech that proposes a commercial transaction. *Id.* at 637. Petitioners maintain that food boards, menus and the like found in convenience and grocery stores satisfy this definition because they do propose commercial transactions.

[28] *Id.* (emphasis supplied).

embedded in the Final Rule's structure is recognition of such variation and tacit admission that caloric calculations will vary within a store and certainly between stores (based on the calculation method chosen by covered establishments at any given time).[29] Similarly, FDA acknowledges in the Final Rule that recommended daily caloric intake for individuals—also a required disclosure—varies significantly between individuals. In other words, the *Final Rule* presents significant questions regarding whether it is requiring the dissemination of false and/or misleading information to consumers.

Additionally, it is far from clear that the Final Rule's required disclosure (or the statutory menu labeling requirement) directly advance a substantial government interest. In the discussion of its purpose, the Final Rule (in a matter of five sentences out of a 105-page publication) cites the obesity rate in the United States, and then suggests—without drawing any direct connection—that providing nutritional information in food establishments may help this problem by enabling consumers "to make informed and healthful dietary choices."[30] Ample evidence shows, however, that calorie labels do *not* change consumers' behavior with respect to the foods they order or the calories they consume.[31] Without direct advancement of a substantial

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[29] *See* Final Rule, 79 Fed. Reg. 71156, 71233 (Dec. 1, 2014) ("[FDA] will assess compliance on a case by case basis, taking into consideration a number of factors, including the covered establishment's nutrition labeling, the method (*e.g.*, laboratory analysis, nutrient database, cookbook, or nutrient information provided on the labels of packaged food) used by the covered establishment to determine nutrition information . . . .").

[30] *Id.* at 71157.

[31] The *New York Times* reported in November 2015 on the experiences of New York City and Seattle, which already have menu labeling programs in place. The story catalogs studies showing that the programs do not work because calorie counts do not decrease the calories customers consume—and by extension, have no benefit in fighting obesity. These studies are notable because they are not based on speculation or conjecture, but rather, real world results of existing programs. In fact, the piece references a systematic review of medical literature on menu labeling through October 2013, which found that the six controlled studies that took place in real world restaurant settings showed that "over all, menu labeling did not produce any significant changes in what people ordered." And, it continues, the Department of Agriculture's Nutrition Evidence Library concluded that "limited and inconsistent evidence exists to support an association between menu calorie labels and food selection or consumption." Finally, the article points out that food items with the lowest reported calories are the most likely to be incorrectly labeled. *See* Carroll, Aaron E., *The Failure of Calorie Counts on Menus,* N.Y. Times (Nov. 30, 2015), available at https://www.nytimes.com/2015/12/01/upshot/more-menus-have-calorie-labeling-but-obesity-rate-remains-high.html?_r=0 (last visited Apr. 2, 2017).

government interest—as appears to be the case here—forced commercial disclosures run afoul of the First Amendment.[32]

For the aforementioned reasons, the Final Rule raises significant First Amendment concerns. NACS and NGA urge FDA to reconsider these important issues as it reevaluates its Final Rule.

5. Implementation of the Final Rule Is Inconsistent with the Administration's Regulatory Agenda and Directives.

The Final Rule is exactly the kind of regulation that the new Administration has opposed and/or halted since January 20 through various Presidential actions. On the Administration's first day in office, White House Chief of Staff Reince Priebus issued a memorandum to the heads of executive departments and agencies calling for a "regulatory freeze pending review."[33] The memorandum instructs the agencies to postpone for 60 days the effective date of regulations published during the previous administration.[34] Although the 60-day delay window since publication of the memorandum has just passed, the Commissioner should nevertheless grant the Petition for the same reasons as similar rules and regulations have been delayed (e.g., to evaluate regulations' consistency with the policies of the new Administration).

Consistent with his agenda to eliminate unnecessary and overly burdensome regulations, the President issued an Executive Order on February 3, 2017, instructing federal agencies to identify two regulations for repeal for every new rule proposed or finalized.[35] The Order recognizes: "it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."[36]

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[32] *See, e.g., Nat'l Ass'n of Manufacturers v. S.E.C. supra* note 26, at 527 (declaring the SEC's conflict minerals reporting obligation on manufacturers "doomed" because the SEC could not show that the disclosure measure it adopted would "'in fact alleviate' the harms it recited 'to a material degree'").

[33] Memorandum from Reince Priebus, Assistant to the President and Chief of Staff, to Heads of Executive Departments and Agencies, *Regulatory Freeze Pending Review* (Jan. 20, 2017), available at www.whitehouse.gov (last visited Mar. 22, 2017).

[34] *Id.*

[35] Executive Order 13771, *Reducing Regulation and Controlling Regulator Costs*, 82 Fed. Reg. 9339 (Feb. 3, 2017).

[36] *Id.*

Then, on February 24, 2017, the President issued an Executive Order on enforcing his regulatory reform agenda.[37] The Order calls for Regulatory Reform Officers and Task Forces in each agency to identify regulations that, among other things, impose costs that exceed benefits or inhibit job creation. Such regulations are to be considered for repeal, replacement or modification because, the Order states: "It is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people."[38]

Based on the foregoing, Petitioners believe the Final Rule falls squarely within the category of regulations disfavored by the Administration—those that are unduly burdensome and costly, and do not provide commensurate benefits. Accordingly, FDA should act now, in accordance with the Administration's policy, to stay and reconsider the Final Rule.

C. Conclusion

For the foregoing reasons, the effective date of the Final Rule should be stayed while FDA staff promulgates a new proposed rule implementing section 4205 of the Affordable Care Act.

IV. Environmental Impact

The action requested herein is subject to categorical exclusion under 21 C.F.R. § 25.32.

V. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), Petitioners will, upon request by the Commissioner, submit additional economic impact information.

VI. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.

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[37] Executive Order 13777, *Enforcing the Regulatory Reform Agenda*, 82 Fed. Reg. 12285 (Feb. 24, 2017).

[38] *Id.*

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