PUBLIC SUBMISSION

As of: December 05, 2011
Received: September 14, 2011
Status: Posted
Posted: October 14, 2011
Category: Association - D0003
Tracking No. 80f19bb6
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0002
National Association of Tobacco Outlets, Inc. - Comment

Submitter Information

Name: Thomas A. Briant
Address: United States,
Submitter's Representative: Thomas A. Briant, Executive Director and Legal Counsel
Organization: National Association of Tobacco Outlets, Inc.

General Comment

See attached file(s)

Attachments

National Association of Tobacco Outlets, Inc. - Comment, NATO Comments on FDA Tobacco Product Reporting Violation Form

NATO

September 14, 2011

Comments on Tobacco Product Reporting Violation Form [Docket No. FDA-2011-N-0553]

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

Dear Food and Drug Administration Representative:

I am submitting these comments on behalf of the National Association of Tobacco Outlets, Inc., a national tobacco retail trade association, regarding the Food and Drug Administration's intent to collect specific information contained in a proposed Tobacco Product Reporting Violation Form. The purpose of the FDA seeking approval from the Office of Management and Budget for this Tobacco Product Reporting Violation Form is to accept consumer and other stakeholder feedback and notification of potential violations of tobacco regulations under the Tobacco Control Act.

In the official notice requesting comments published in the Federal Register on August 22, 2011, the FDA has requested comments on four topics. Each of the topics is listed below followed by NATO's comments on that particular topic.

Topic 1: Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

The Tobacco Control Act does not contain any requirement that the FDA request or accept notification of possible tobacco regulation violations from the public or other stakeholders. With no directive from Congress in the provisions of the Tobacco Control Act to request or accept information on potential violations, there is no demonstrated need to collect reports of potential violations in order to allow the FDA to properly perform its regulatory functions.

In fact, under Section 103 of the Tobacco Control Act, the FDA was granted the authority to contract with states to conduct compliance inspections on retailers and submit reports of potential violations. The specific language granting this authority in Section 103 is as follows:

> "For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with enforcement of this Act."

The contracts entered into between the FDA and various states to conduct compliance inspections on retail stores follow a very specific protocol that requires extensive training of state agency personnel by the FDA regarding the terms of the Tobacco Control Act, how to conduct a retail store compliance inspection, and how to recognize and report a potential violation of a tobacco regulation. This strict protocol is used to ensure that inspectors are knowledgeable about the Tobacco Control Act and that the inspections are conducted fairly and responsibly. If Congress had intended the general public to be called upon to police retailers that sell tobacco products and report potential regulatory violations, then such intent would have been stated within the Tobacco Control Act itself.

Moreover, based on the FDA's Center for Tobacco Products policy on issuing warning letters or civil penalty violation letters to retailers, even a specially trained state compliance inspector is not qualified to make a final decision on whether a retailer violated a tobacco regulation. Rather, an official within the Center for Tobacco Products' Office of Compliance is required to review every state report in which a potential violation is cited and make an independent determination whether a violation occurred and, if so, send out a warning letter or a civil penalty letter to the retailer involved.

To reiterate this point, while the Tobacco Control Act allows the FDA to contract with the states for compliance enforcement, the law is devoid of any language directing the FDA to reach out to the general public and other stakeholders to report possible violation. Without any formal training about the terms of the Tobacco Control Act and the actual tobacco regulations that retailers must follow, the FDA cannot justify seeking OMB approval to request impromptu reports from the public and possibly anti-tobacco advocacy organizations which would require detailed knowledge about the law and specific information about a potential violation.

The information being requested by the FDA in these reports from the public would include: (1) the date of the violation, (2) the product type (e.g., cigarette, roll-your-own tobacco, or smokeless tobacco), (3) the tobacco brand name, (4) a description of the potential regulatory violation, and (5) the name, address, phone number, website address and e-mail address of the potential violator. If state agencies are required to undergo significant training to conduct retail inspections and report possible violations, either the same standards need to be required of the general public and other stakeholder groups or the FDA should consider not proceeding with the reporting form. It is unrealistic to believe that the average citizen would have the knowledge and qualifications to determine whether a retailer has possibly violated a tobacco regulation.

At the same time, an approval of the FDA's violation reporting form by the OMB could result in specific retailers being singled out for potential violation reports by members of the general public or stakeholder organizations. How would such reports that target a specific retailer have any utility to the overall goal of responsible enforcement of the Tobacco Control Act?

Topic 2: The accuracy of the FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

Given the number of detailed facts that the FDA requests the public and stakeholders submit about a potential violation, the time to collect that data may take significantly longer than the ten minutes estimated by the FDA. Unless a member of the public is present in a store at the exact time a potential violation occurs such as the sale of tobacco to a minor, that citizen may very well need to remain in the store for a long period of time watching transactions before a situation arises that might be considered a violation. Also, how is a member of the public supposed to remember all of the detailed information that the FDA is requesting without also checking other sources for such facts including the employee's name, the employee's e-mail address, the website address of the store, etc. In short, the time burden estimated by the FDA appears to be substantially lower than what may actually be the case in a real world situation.

Also, the notice published in the Federal Register does not describe the methodology used by the FDA to estimate that some 1,000 reports of potential violations will be made each year for the next three years. The only benchmark used by the FDA is the receipt of "several reports via the Internet or e-mail" after the sale of flavored cigarettes was prohibited under the Tobacco Control Act in September of 2009. How does receiving approximately three reports about flavored cigarettes over a two year time span translate into 1,000 reports of potential violations each year for the next three years? The validity of the FDA's methodology cannot be supported or contested when the FDA does not explain the methodology. If the FDA decides to pursue OMB approval of the violation reporting form, then the FDA should consider rescinding this notice and reissue the notice with a more detailed explanation of the agency's methodology and assumptions used to calculate the burden of reporting possible tobacco regulatory violations.

Topic 3: Ways to enhance the quality, utility, and clarity of the information to be collected.

As noted above, if the general public and stakeholder organizations are not required to undergo extensive training on the specific regulatory requirements of the Tobacco Control Act, the quality of potential violation reports will be very low and even suspect. Moreover, a scenario could develop where members of the general public and/or stakeholder organizations target certain retail stores for the purpose of filing reports of possible regulatory violations. This could even rise to the level of harassment when a retailer abides by the tobacco regulations only to have inaccurate or false reports filed by the public or stakeholder organizations. That kind of behavior would call into question the very usefulness and utility of any such reports made to the FDA. Moreover, has the FDA considered what corrective action the agency would take against the person or entity that files a false or inaccurate report against a retailer? What is the retailer's recourse in the event a false or inaccurate report is filed? Are there any due process safeguards afforded a retailer that finds itself the target of a false or inaccurate report?

Based on these scenarios and questions, allowing the public and stakeholder organizations to file reports of potential violations may actually undermine the FDA's ability to administer and enforce the tobacco regulations. Rather, the most fair and reasonable means to report potential violations of the tobacco regulations is through FDA sponsored state compliance inspection

program that must be conducted according to a set of rules and utilizes knowledgeable inspection officers that employ uniform inspection techniques.

Topic 4: Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The real burden of filing reports of potential regulatory violations will fall on the retailers that are the subject of the reports. NATO's understanding is that the FDA will need to follow up on these reports and might involve additional compliance inspections of retailers. This will subject retailers to greater scrutiny even though the reports may be inaccurate, lack specific facts, or be outright false. The real question for the FDA and the OMB to consider is how to ensure that any such reports of potential violations have a basis in fact and how to lessen the burden of enforcement on law-abiding retailers that are targeted by members of the public or stakeholders.

Sincerely,

Thomas A. Briant

NATO Executive Director

PUBLIC SUBMISSION

As of: December 05, 2011
Received: September 15, 2011
Status: Posted
Posted: October 14, 2011
Category: Private Industry - C0003
Tracking No. 80f1c9cf
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0003
Dan L Littlefield - Comment

Submitter Information

Name: Dan L Littlefield
Address:
OR,
Organization: The Smoke Shack

General Comment

The FDA's proposal to solicit reports of tobacco industry violations
from the general public does'nt bother me none; i'm not hiding any Jews in my attic.....Oh wait; wrong century/country....
Sorry, forgot where I was for a moment.
Never mind

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 07, 2011
Status: Posted
Posted: October 14, 2011
Category: Association - D0003
Tracking No. 80f4ed83
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0004
NATO: National Association of Tobacco Outlets, Inc. - Comment

Submitter Information

Name: Thomas A. Briant
Address:
MN,
Submitter's Representative: Thomas A. Briant
Organization: NATO: National Association of Tobacco Outlets, Inc.

General Comment

See attached file(s)

Attachments

National Association of Tobacco Outlets, Inc. - Comment, NATO Supplemental Comments on FDA Tobacco Product Reporting Violation Form

NATO

October 7, 2011

Supplemental Comments on Tobacco Product Violations Reporting Form
[Docket No. FDA-2011-N-0553]

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

Dear Food and Drug Administration Representative:

I am submitting this set of supplemental comments on behalf of the National Association of Tobacco Outlets, Inc. (NATO), a national tobacco retail trade association, regarding the Food and Drug Administration's intent to collect specific information contained in a proposed Tobacco Product Violations Reporting Form (Form FDA 3779). NATO submitted an initial set of comments on this docket to the FDA on September 14, 2011.

The purpose of this set of supplemental comments is to bring to the attention of the FDA how the proposed Violations Reporting Form is contrary to and may likely violate Executive Order No. 13563 entitled "Improving Regulation and Regulatory Review" issued by President Barack Obama on January 18, 2011. The intent of this Executive Order is to eliminate unnecessary and wasteful government regulations. Below are NATO's comments on how the proposed Violations Reporting Form is contrary to and may violate two important sections of the Executive Order.

Executive Order Section 1: General Principles of Regulation

This section of the Executive Order states, in part, that a regulation must (1) promote predictability and reduce uncertainty, and (2) measure, and seek to improve, the actual results of regulatory requirements.

Issuing a Violations Reporting Form to allow the public and other stakeholders to submit reports of possible retail violations of FDA tobacco regulations decreases predictability and increases uncertainty. This regulation essentially deputizes the public and other stakeholder groups without any guidance or training about the FDA's retail tobacco regulations to police retailers that sell tobacco products. That is, neither the public nor other stakeholder groups will have the benefit of being educated about retail regulations or how to identify a possible violation. This is

in stark contrast to the FDA's extensive training of state agency personnel in how to conduct FDA sponsored retail compliance inspections. The result will likely be inaccurate and unverifiable reports of possible violations filed by the public and other stakeholders that the FDA would be obligated to corroborate in a manner that has yet to be determined.

In addition, the actual wording of the proposed Violations Reporting Form is vague and invites unsubstantiated and even false reports of possible violations. Below is a copied section of the actual form to report the "potential violation type".

Potential violation type (choose all that apply)

- ☐ Sales to minors
- ☐ Flavored cigarette sales
- ☐ Advertising/promotion/marketing
- ☐ Free samples
- ☐ Vending machine/self-service display/direct access to cigarette or smokeless tobacco
- ☐ Sale of cigarettes in packs less than 20
- ☐ Other

It appears that the FDA drafted this form to make it as simple as possible for a person or stakeholder group to fill out and report a possible violation. However, in doing so, the ambiguity of the form itself and the vagueness of possible answers will guarantee ambiguous reports and degrade, not improve, the results of the regulatory action.

An excellent example of a similar kind of ambiguity is found in "Break the Chain" brochures drafted by FDA Center for Tobacco Products staff. Although the Tobacco Control Act as passed by Congress only enacted regulations on cigarettes, roll-your-own tobacco and smokeless tobacco products, the Break the Chain materials often refer to "tobacco products" without limiting the reference to just cigarettes, roll-your-own tobacco and smokeless tobacco. Given this inaccuracy in the FDA's Break the Chain materials, how is an uneducated public expected to know which kinds of tobacco products are regulated and which kinds are not subject to regulation for purposes of submitting possible violation reports?

Even the Tobacco Product Violations Reporting Form itself makes no mention that possible violations are limited to cigarettes, roll-your-own tobacco and smokeless tobacco products. By not including any explanation about what tobacco products are regulated, the reporting form only exacerbates the ambiguity for the public.

Moreover, while the form provides for reporting a possible violation on advertising, there are two pending federal lawsuits challenging the FDA cigarette advertising restrictions and regulations and the FDA has also postponed any enforcement action on the ban on outdoor tobacco advertisements. Until these lawsuits and the outdoor advertising issue are finally resolved, how can the FDA accept a report from the public or other stakeholder group that has a check mark in the box for "Advertising/promotion/marketing"?

Regarding the "Free samples" answer, the brevity of this selection fails to inform the person making a report which kind of tobacco products are covered by the ban on samples and does not disclose the exemption for sampling smokeless tobacco products in adult-only facilities. This

same exemption question would arise in the "Vending Machine/self-service displays" answer selection since adult-only tobacco stores are allowed to have self-service displays of cigarettes, roll-your-own tobacco and smokeless tobacco. The absence of an explanation of these exemptions on the Violations Reporting Form will result in the filing of false reports against retailers that are acting legally within the terms of the exemption.

In short, the Violations Reporting Form does not comply with either of the two requirements in Section 1 of the President's Executive Order because the form allows for inaccurate and even false reports of possible violations, which only adds uncertainty to the enforcement of the existing regulations.

Executive Order Section 3: Integration and Innovation

As a part of Section 3 of the Executive Order, federal agencies are required to promote coordination, simplification and harmonization between agencies because "[s]ome sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent or overlapping." The proposed regulation for the Violation Reporting Form is redundant and overlapping in several respects. First, the FDA tobacco regulatory law requires the agency, where feasible, to contract with state agencies to conduct retail compliance inspections to enforce the law. As a part of this mandate, the FDA trains state agency officials about the tobacco regulations and how to identify potential violations. Since the FDA already contracts with 35 states and the District of Columbia to conduct retail inspections, with a goal of contracting with all 50 states in the near future, seeking the assistance of an untrained public to report possible violations is redundant and inconsistent with the Congressional directive that the FDA contract with only state agencies.

Second, although the Executive Order is meant to minimize redundancy among federal agencies, there is another overlapping layer of retail compliance inspections at the local and state levels. Many cities and states have adopted tobacco retail licensing laws that incorporate compliance inspections on tobacco retailers as a routine method to ensure compliance. With the FDA sponsored compliance inspections conducted by state agencies being a second means of enforcement, adding a third layer of compliance reporting by the public and other stakeholder groups is not only redundant, but simply unnecessary.

For the reasons outlined above, the FDA's proposed notice of issuing a Tobacco Product Violations Reporting Form is certainly contrary to and could very well violate the President's Executive Order. As a result, the FDA should rescind the notice to request approval of the Violations Reporting Form from the Office of Management and Budget and not purse any further action on this proposed regulatory matter.

Sincerely,

Thomas A. Briant

NATO Executive Director

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Thomas Farley, M.D., M.P.H.
Commissioner

General Counsel's Office
42-09 28th Street, 14th Fl.
Queens, NY 11101
Tel.# 347-396-6116

October 12, 2011

www.regulations.gov

RE: FDA-2011-N-0553 Agency Information Collection Activities; Proposed Collection; Tobacco Product Reporting Violation Form

To Whom It May Concern:

On behalf of the New York City Department of Health and Mental Hygiene (DOHMH), I write in response to the request for comments on the agency information activities proposed collection comment request. Given the limited resources available to federal, state, and local officials, we applaud FDA's proactive engagement with the public to assist in identifying violations and enable better enforcement of the Tobacco Control Act.

We feel the proposed collection of information is necessary for the proper performance of FDA's functions. Violations can occur in a number of settings and engaging the public in a quick and simple way to report those violations will make it easier for FDA to enforce provisions of the Tobacco Control Act.

The proposed time for any one individual to report a violation is small, and we agree with FDA's assessment of this. The use of automated smart phone technology to make data collection easier is also a positive step in engaging the consumer and minimizing burden.

That said, we think that enforcement could be further enhanced if FDA were to share information about potential violations with local jurisdictions since some violations of the Tobacco Control Act may also be illegal under state and local laws. Localities may be able to respond quicker to such reports, particularly in jurisdictions that do not yet have enforcement contracts with the FDA. In addition, this will increase the benefit and use of the technological innovations (such as the smartphone application for reporting) that are being developed by the FDA. This is a positive step forward to ensure compliance with federal law, but to maximize its impact on a local level, we could also encourage the FDA to make the public aware of this system to report potential violations.

In order to facilitate sharing of the information with localities, FDA should consider adding a field asking the submitter whether he or she would like the information being reported to be shared with local government authorities. Local

governments could establish automated communications with FDA to obtain any violation reports in their jurisdiction which would enable local jurisdictions to further investigate violators as well and hold them accountable to local and state laws.

We appreciate the opportunity to comment on this request for proposed agency information collection. The reporting of possible violations of the Tobacco Control Act in real-time digital format would make it easier for our jurisdiction and others to act on information and tips and we hope that FDA will want to maximize its investment in these technological innovations by sharing the data with local enforcement authorities.

Sincerely,

Thomas Merrill
General Counsel

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 17, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f540d1
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0006
Anonymous - Comment

Submitter Information

Organization: Circle-K

General Comment

The FDA does not have the authority to request violation reports from the public. FDA's state inspectors are highly trained. The public has no training on howto perform an inspection. The public may have other motives by targeting law abiding retailers. Inaccurate reporting will cause undue burden on a law abiding retailer.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 17, 2011
Status: Posted
Posted: November 03, 2011
Category: Consumer Group - B0003
Tracking No. 80f543d8
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0007
Brenda Fisher - Comment

Submitter Information

Name: Brenda Fisher
Address:
WA,
Submitter's Representative: Thomas Briant
Organization: NATO

General Comment

1. The Family Smoking Prevention and Tobacco Control Act granting the FDA the authority to regulate tobacco products does not contain any provision allowing the FDA to request possible tobacco regulation violation reports from the public or other stakeholder groups.

2. The FDA has currently contracted with 38 states and the District of Columbia to conduct retail compliance inspections and these state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection, and how to recognize a potential tobacco regulation violation. This same training requirement is not required of the public or other stakeholder groups which means that they may not be knowledgeable enough about the tobacco regulations to understand what may or may not be a violation. The result could be the filing of inaccurate or false violation reports.

3. The use of this reporting form could also lead to members of the public and stakeholder groups targeting and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports.

4. An inaccurate or false report will result in the FDA inspecting a law-abiding retailer and burdening the retailer with unnecessary regulatory inspections.

5. President Barack Obama issued Executive Order No. 13563 in January of 2011 requiring government agencies to eliminate wasteful and unnecessary regulations. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary because state agencies have been thoroughly trained to conduct these inspections. This kind of action is contrary to the President's Executive Order.

6. The form proposed by the FDA for reporting possible violations is so general that the possible violations listed are vague and will lead to inaccurate, misleading and false reports. This kind of vagueness is also in conflict with the specific requirements of the President's Executive Order.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 19, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f56253
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0008
Kocolene Marketing, LLC - Comment

Submitter Information

Organization: Kocolene Marketing, LLC

General Comment

Dear FDA Representative,

In regards to the FDA tobacco product violation reporting form...as a leader in the tobacco store/convenience store industry, I am aware of the Family Smoking Prevention Tobacco Control Act giving the FDA the authority to regulate tobacco products. However, I am unaware of the act allowing the FDA to request tobacco regulation violation reports from the public or other groups. Is the public properly trained to check for compliance? The tobacco rules and regulations are quite complicated these days. Having untrained people reporting violations could result in inaccurate or false violation reports. This could damage the reputation of a business. Doesn't all this go against President Obama's executive order 13563 filed earlier this year to STOP unnecessary regulations such as this?

-Andrea Myers
Executive Vice President
Kocolene Marketing, LLC
Seymour, IN
30 retail stores

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f56c27
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0009
Cumberland Farms Inc. - Comment

Submitter Information

Name: Anne Flint
Address:
MA,
Organization: Cumberland Farms Inc.

General Comment

Cumberland Farms takes responsibility for and pride in being a "responsible retailer". That being said, we support the FDA's program of contracting states for the retail compliance inspections. We believe that the extensive training that these inspectors receive qualifies them to conduct these inspections. However, we DO NOT support the FDA's plan to allow the public and anti-tobacco organizations to report possible retail violations. It is our understanding that this same training will not be required of the general public. This type of uneducated reporting could lead to groups targeting and harassing responsible retailers by submitting inaccurate or possibly even false violation reports. These inaccurate reports could result in extra work for both the FDA and the retailers who are selling legal products.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f57244
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0010
Megan Ann Wisbrock - Comment

Submitter Information

Name: Megan Ann Wisbrock
Address:
IA,
Organization: Kum and Go

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain any provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting

and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.

Finally, President Obama s Executive Order No. 13563 required government agencies to eliminate wasteful and unnecessary regulations. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary because state agencies have been thoroughly trained to conduct these inspections. The proposed FDA action is contrary to the President's Executive Order.

For the r

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f5728d
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0011
Jeffrey Steinbock - Comment

Submitter Information

Name: Jeffrey Steinbock
Address: United States,
Organization: Uhle Tobacco Company

General Comment

I am concerned about the lack of safeguards to prevent persons with other intentions, from submitting false claims against retailers.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: DoNotPost
Category: Individual Consumer
Tracking No. 80f57315
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-DRAFT-0012
Anonymous - Comment

Submitter Information

Address:
IA,
Organization: Kum Go

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain any provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders. Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.
The use of the proposed reporting form may lead to members of the public and others targeting and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.
Finally, President Obama□s Executive Order No. 13563 required government agencies to eliminate wasteful and unnecessary regulations. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.
For the reasons stated above, I respectfully request FDA not pursue any further action on this proposed regulatory matter.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f5729b
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0012
Fred Hoyt - Comment

Submitter Information

Name: Fred Hoyt
Address:
LA,
Submitter's Representative: Fred Hoyt
Organization: K F Inc

General Comment

Most States, as does Louisiana, have a FDA Policeing authority with the power to cite warnings or infractions. Why would we need to create a whirlwind of "public witch hunting" for possible violators. This would only present a bottleneck for the agency in charge of running down these "leads"?????

Please do not inhibite the ATC from doing their job!!!!

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: DoNotPost
Category: Individual Consumer
Tracking No. 80f57301
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-DRAFT-0013
Jodi A. Gehrts - Comment

Submitter Information

Name: Jodi A. Gehrts
Address:
IA,
Organization: Kum Go, LC.

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain a provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting and harassing law-abiding retailers by submitting inaccurate or possibly even false violation

reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.

Finally, President Obama's Executive Order N. 13563 required government agencies to eliminate wasteful and unnecessary regulation. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.

For the reasons stated above, I respectfully request FDA not purse any further action on this proposed regulatory matter.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f5734d
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0013
John T Feldman - Comment

Submitter Information

Name: John T Feldman
Address:
IA,
Organization: Kum Go, L.C.

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain a provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting

and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.

Finally, President Obama's Executive Order N. 13563 required government agencies to eliminate wasteful and unnecessary regulation. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.

For the reasons stated above, I respectfully request FDA not purse any further action on this proposed regulatory matter.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f5740e
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0014
Keith Clark - Comment

Submitter Information

Name: Keith Clark
Address:
IA,
Organization: Kum Go

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain a provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting

and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.

Finally, President Obama's Executive Order N. 13563 required government agencies to eliminate wasteful and unnecessary regulation. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.

For the reasons stated above, I respectfully request FDA not purse any further action on this proposed regulatory matter.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 20, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f5788d
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0015
Jeffrey H Toole - Comment

Submitter Information

Name: Jeffrey H Toole
Address:
WA,
Submitter's Representative: Owner
Organization: Tobacco, Beer More

General Comment

I oppose the fact that anyone could submit a false or misleading complaint against a retailer.

The FDA has contracted with states to do compliance checks. These people have been trained on what the law is.

There is nor provision in the Family Smoking Prevention and Tobacco Control Act giving the FDA the authority to ask untrained people to report possible violations.

This would and additonal and unnecessary paper work for the FDA.

As stated above, I oppose this additional form of checks being conducted by untrained people.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 21, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f581c0
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0016
Richard L Ginther - Comment

Submitter Information

Name: Richard L Ginther
Address:
IA,
Submitter's Representative: Richard Ginther
Organization: Kum Go

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain a provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.

Finally, President Obama's Executive Order N. 13563 required government agencies to eliminate wasteful and unnecessary regulation. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.

For the reasons stated above, I respectfully request FDA not purse any further action on this proposed regulatory matter.

October 21, 2011

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

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Form
Docket No. FDA 2011 N 0553

The National Association of Convenience Stores (NACS) appreciates this opportunity to provide comments on the Food and Drug Administration (FDA or the Agency) Notice regarding the tobacco product reporting violation form.[1] As further articulated below, we believe permitting members of the public to report alleged violations of FDA s tobacco regulations is unjustified.

NACS is an international trade association representing more than 2,100 retail and 1,500 supplier company members. NACS member companies do business in nearly 50 countries worldwide, with the majority of members based in the United States. While 49 of the top 50 convenience store companies in the United States are members of NACS, the majority of our members are small, independent operators. More than 70 percent of our membership is composed of companies that operate ten stores or less, and more than 60 percent of our membership operates five stores or less. Nearly 40 percent of our membership operates a single store.

Sales of cigarette and other tobacco products comprise more than 36 percent of the in-store sales at convenience stores, and thus are vital to the economic viability of the convenience store industry. NACS and its members are committed to selling all of our merchandize in a lawful manner; we have devoted a substantial amount of time and resources to ensuring that convenience store operators are equipped to comply with federal, state, and local tobacco regulations. This includes our work with *We Card*, a non-profit organization of which NACS is a founding member that provides tobacco retailers with multi-level training and educational products and services. *We Card* helps retailers prepare employees to set clear expectations and provide continuous feedback in an effort to prevent underage access to tobacco.

In addition to *We Card*, NACS has provided both formal and informal guidance to its members regarding FDA s restrictions on tobacco sales and marketing. This has taken the form of legal memoranda, seminars and webinars, and individual correspondence with membership. Our guidance has been based on the language of the Tobacco Control Act and its implementing regulations, as well as the guidance documents FDA has released for industry.

The law and regulations in this area do not raise the concept of members of the public reporting possible regulatory violations. Congress included no directive in the Tobacco Control

[1] 76 Federal Register 52333 (August 22, 2011).

Act that FDA accept such reports, and FDA included little indication in its guidance documents that this would be part of its enforcement strategy. Indeed, FDA's "Guidance for FDA and Tobacco Retailers [on] Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers" includes no reference to members of the public reporting alleged violations to FDA. FDA's Draft Guidance on "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" contains no notice to retailers that FDA will be permitting members of the public to report alleged violations. Instead, it limits all discussion of this prospect to the final sentence of the document noting the website and phone number individuals can use to report alleged violations. This, to us, is emblematic of the various issues we have had with (and filed comments on) the Agency's regulatory process, whereby industry is not provided with a clear picture of the regulatory environment and FDA's plans.

Beyond the fact that retailers were given little notice that their customers may be masquerading as vigilante FDA enforcement agents, this policy will be of little utility to the Agency. Members of the public have a minimal understanding of the intricacies of FDA's tobacco regulations. In part due to the complexity of its regulations, FDA requires state agents who conduct compliance inspections to submit to an extensive training program regarding the Tobacco Control Act's terms, how to properly inspect retail outlets, and how to recognize and report a potential violation. Without such measures, state agents would not be able to adequately inspect for violations.

By contrast, members of the public at large lack any formal training as to how inspections can be conducted and even as to the terms of the statute they would be enforcing. In requiring agents of states with which it contracts to conduct retailer inspections to be tested, FDA rightly recognized that conducting inspections requires a certain amount of knowledge and skill. We urge the Agency not to forget this fact as it moves forward.

Finally we are happy that FDA recognizes that its authority in regard to these inspections is limited. "Callers are able to report potential violations of the Tobacco Control Act and *FDA will conduct targeted follow up investigation based on information received.*"[2] Thus, it appears that the Agency does not plan on issuing Warning Letters or civil money penalties solely based on reports by members of the public (as it does for reports by state inspection agents).

This limitation must remain in place in order to avoid conflict with the Tobacco Control Act which only allows FDA or states with which it contracts to perform inspections that may lead to actual violations under the law. The Tobacco Control Act lists various means by which FDA can conduct retailer inspections.[3] By listing those methods which are permissible, Congress excluded any additional methods (such as inspections by members of the public). "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or in

[2] 76 Fed. Reg. 52334 (emphasis added).
[3] 21 U.S.C. "372(a) (permitting federal officers of HHS to conduct examinations, and allowing HHS to contract with states to carry out inspections).

ancillary provisions.[4] This was the foundation of the Supreme Court's reasoning in concluding in the mid-1990s that FDA lacked the authority to regulate tobacco.[5] It also underlays the statutory canon *expressio unius est exclusion alterius* (the inclusion of one is the exclusion of others), which stands for the proposition that "Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of a contrary legislative intent."[6]

We appreciate that the FDA recognized these limitations and will not issue Warning Letters or civil money penalties based on reports filed by members of the public and instead will only do so based on its own (or a state's) inspections.

We appreciate the Agency's willingness to consider our comments, and stand ready to provide any further assistance to the Agency as it moves forward.

Sincerely yours,

Lyle Beckwith
Senior Vice President, Government Relations

[4] *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001). *See also MCI Telecommunications Corp. v. AT&T*, 512 U.S. 218, 231 (1994) (conferral of authority to "modify" rates was not a cryptic conferral of authority to make filing of rates voluntary).

[5] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 ("Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion.").

[6] *Andrus v. Glover Const. Co.*, 446 U.S. 608, 616-17 (1980).

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 21, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f58415
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0018
Levin Ginsburg - Comment

Submitter Information

Name: Jonathan M. Weis
Address:
IL,
Submitter's Representative: N/A
Organization: Levin Ginsburg

General Comment

RE: Comment Regarding Docket No. FDA-2011-N-0553 (Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form)

Dear Food and Drug Administration:

Our comments are set forth on the uploaded attachment to this coment. We are submitting these comments because we are a law firm that focuses a portion of our practice representing the interests of tobacco manufacturers, distributors and retailers. This comment addresses FDA s intent to collect specific information contained in a proposed tobacco product reporting violation form, no. 3779.

Jonathan M. Weis
Partner
Levin Ginsburg
180 North LaSalle Street, Suite 3200
Chicago, IL 60601-2800

312-368-0100

Attachments

Levin Ginsburg - Comment, SCAN9856□000

LEVIN GINSBURG

ATTORNEYS AT LAW

180 NORTH LASALLE STREET ▪ SUITE 3200
CHICAGO, ILLINOIS 60601-2800
312.368.0100

October 21, 2011

Via Certified Mail, Return Receipt Requested and Email Transmission Via regulations.gov

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

RE: Comment Regarding Docket No. FDA-2011-N-0553 (Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form)

Dear Food and Drug Administration:

We are submitting these comments because we are a law firm that focuses a portion of our practice representing the interests of tobacco manufacturers, distributors and retailers. This comment addresses FDA's intent to collect specific information contained in a proposed tobacco product reporting violation form, no. 3779, which would replace the current form 3734 titled "Information Regarding Cigarettes With Characterizing Flavors." According to FDA, it is requesting Office of Management and Budget (OMB) approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (the "Act"). Part of FDA's related enforcement strategy is to accept information from the public about alleged violations of the Act and to allow callers to report potential violations of the Act so that FDA can conduct targeted follow up investigations based on information received. In order to expedite this reporting, FDA has developed a form that will be used to solicit this information from the caller (FDA Form 3779, Tobacco Product Violations Reporting), which is expected to replace current FDA Form 3734 for Cigarette Flavor Ban Violations. FDA wishes to post the new form on its website so that information may be submitted by the public by completing the form online. There are several comments we wish to make with respect to the notice. Certain of these comments echo the National Association of Tobacco Outlets' comments. Furthermore, the comments below set forth reasons why there should not be any reporting form posted by FDA, but that if one is posted, it should be the new Form 3779, with a few caveats.

First, the Act does not contain any requirement that FDA seek out or request comments from the general public regarding potential violations of the Act. Within the last several months, FDA has contracted with various state agencies to conduct inspections of retail premises and no doubt is expending great resources in doing so, making it unnecessary to request information from the

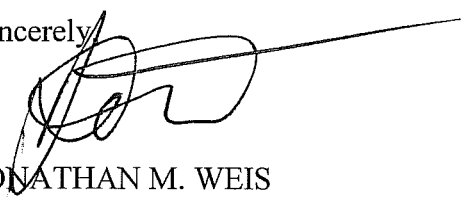
public regarding alleged violations. Furthermore, Illinois, where we are located, as well as most, if not all, States have city, county as well as statewide tobacco investigatory enforcement units which routinely enforce local ordinances and state law relating to tobacco, and can and do report to FDA. It is unlikely that any member of the public is as highly trained as an FDA investigator, or the various state agencies with which FDA has contracted, regarding the terms of the Act, how to conduct an inspection and how to recognize a potential violation. As a result, FDA could find itself dealing with inaccurate reports and reports which do not even address a violation of the Act but which FDA nonetheless has to spend time and taxpayer dollars reviewing. This type of permissiveness with respect to general reporting from the public can lead to anti-tobacco organizations filing unjustified and frivolous reports and industry competitors filing unjustified and frivolous reports against one another. This will result in low quality reports of very little, if any, value. Neither the proposed form 3779 nor current form 3734 requires that the report be filed under oath subject to penalty of perjury. Given the risks (detailed above) associated with allowing anybody to file a report, there should be some assurance that if form 3779 is approved that it will not be abused. The repercussions to businesses that are subject to false or unjustified reports can be severe, and there should be repercussions against the person filing false or unjustified and frivolous reports.

Form 3779 must also state very clearly at the top that possible violations are limited to only cigarettes, roll-your-own tobacco and smokeless tobacco and not any and all imaginable tobacco products. We understand that the fourth line of the proposed form stating "Description of Product Type" references: "cigarette, smokeless, roll-your-own, and other." We strongly suggest that the term "other" be removed because it leaves so much to the imagination and will not make any sense to the general public or even many trained investigators. For example, members of the public and even trained investigators may not be aware that FDA is not authorized to regulate pipe tobacco under the Act. Reports regarding pipe tobacco would result in a waste of time and resources. In addition, for clarification purposes the word "tobacco" should be added after "smokeless" and "roll-your-own."

In conclusion, it would be most appropriate for there to be no tobacco product reporting forms posted. If an interested consumer or stakeholder is truly interested in reporting a violation, it goes without saying that they can always contact or write to FDA. However, if a reporting form is to be posted, the new form 3779 is certainly an improvement over form 3734 which is woefully inadequate and insufficient, as it does not cover any potential violations but for those related to flavored cigarettes. If nothing else, form 3779 is preferable, but the product description section should only reference: "cigarettes, smokeless tobacco and roll-your-own tobacco."

Should you have any questions with respect to the foregoing, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,



JONATHAN M. WEIS
jweis@lgattorneys.com

JMW/dl

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 21, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f5847f
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0019
Anonymous - Comment

Submitter Information

Address:
PA,
Submitter's Representative: Lee Silverman
Organization: Klafter's Inc.

General Comment

I want submit a comment in regard to the proposal under consideration for allowing the general public the authority to police retail tobacco dealers for supposed tobacco violations. Aside from the fact that no where in the Family Smoking Prevention and Tobacco Control Act is this authority granted, how would any individual, other than a trained agent, have an idea of what is or what is not a violation? To support this, even the agency inspectors have not been able to establish consistent methods yet. This move would open the door and give the ability for every and any individual that has an issue or grudge against any retail business the use of this authority as a means of causing financial and time loss to a business by filing fraudulent reports whether on purpose or by accident. There are so many inspections taking place at the retail level by qualified agents that the last thing needed is an untrained general public being asked to be whistle-blowers for in an area that they have no formal knowledge. I would think that any filed complaint would be open to scrutiny legally causing unnecessary expense and time to the business and FDA. In addition, I would think that fraudulent reports could open the accuser to a legal action by the business. Businesses selling tobacco are well aware of the requirements that need to be adhered to and the last thing needed are untrained individuals using non specific reporting formats indirectly representing the interests of the FDA

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 21, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f58497
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0020
Charles Walter Campbell - Comment

Submitter Information

Name: Charles Walter Campbell
Address: United States,
Organization: Kum Go, L.C.

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain a provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting and harassing law-abiding retailers by submitting inaccurate or possibly even false violation

reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites inaccurate and misleading reports.

Finally, President Obama's Executive Order N. 13563 required government agencies to eliminate wasteful and unnecessary regulation. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.

For the reasons stated above, I respectfully request FDA not purse any further action on this proposed regulatory matter.

PUBLIC SUBMISSION

As of: December 05, 2011
Received: October 21, 2011
Status: Posted
Posted: November 03, 2011
Category: Private Industry - C0003
Tracking No. 80f586db
Comments Due: October 21, 2011
Submission Type: Web

Docket: FDA-2011-N-0553
Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form.

Comment On: FDA-2011-N-0553-0001
Agency Information Collection Activities; Proposals, Submissions, and Approvals: Tobacco Product Reporting Violation Form

Document: FDA-2011-N-0553-0021
Jason Bassett - Comment

Submitter Information

Name: Jason Bassett
Organization: Kum Go, L.C.

General Comment

The Family Smoking Prevention and Tobacco Control Act granting The U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products does not contain a provision allowing the solicitation or reporting of possible tobacco regulation violations from the public or other stakeholders.

Currently, FDA has contracted with 38 states and the District of Columbia to conduct retail compliance inspections. As part of the contract, state inspectors receive extensive training on the tobacco regulations, how to conduct a compliance inspection and how to recognize a potential tobacco regulation violation. The training requirement for state inspectors would not be required of the public or other stakeholders. As such, reports would be made by those who do not possess knowledge of tobacco regulations or understand what may or may constitute a violation. The result may very well be the filing of inaccurate or false violation reports. An inaccurate or false report will result in the inspection of law-abiding retailers and burdening the retailer with unnecessary regulatory inspections. In addition, false or inaccurate reports would further drain precious state resources that would be better used in monitoring non-compliant retailers.

The use of the proposed reporting form may lead to members of the public and others targeting and harassing law-abiding retailers by submitting inaccurate or possibly even false violation reports. Furthermore, the form proposed by FDA is so general and vague that it virtually invites

inaccurate and misleading reports.

Finally, President Obama's Executive Order N. 13563 required government agencies to eliminate wasteful and unnecessary regulation. Authorizing the public and anti-tobacco organizations to report possible retail violations is unnecessary and contrary to the President's Executive Order.

For the reasons stated above, I respectfully request FDA not purse any further action on this proposed regulatory matter.

SHEPPARD MULLIN
SHEPPARD MULLIN RICHTER & HAMPTON LLP
ATTORNEYS AT LAW

1300 I Street, NW | 11th Floor East | Washington, D.C. 20005-3314
202-218-0000 *office* | 202-218-0020 *fax* | *www.sheppardmullin.com*

Seth A. Mailhot
Writer's Direct Line: 202-469-4980
smailhot@sheppardmullin.com

October 21, 2011

Our File Number: 27XG-161738

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

Re: Comments on Tobacco Product Reporting Violation Form
[Docket No. FDA-2011-N-0553]

Dear Sir or Madam:

We write to comment on the U.S. Food and Drug Administration's intent to collect specific information contained in a proposed Tobacco Product Reporting Violation Form, as published in the Federal Register on August 22, 2011 (76 Fed. Reg. 52,333). These comments represent the viewpoint of Smoker Friendly, a coalition of family-owned, small businesses operating tobacco retail establishments committed to responsibly retailing tobacco products. Combined, Smoker Friendly's members operate over 700 retail facilities, which employ over 3,000 employees and service over 1,000,000 customers of legal age, with annual sales of approximately $750,000,000.

In its August 22 notice, the U.S. Food and Drug Administration ("FDA") requested comments regarding its proposed Tobacco Product Reporting Violation Form ("Reporting Form"). The Reporting Form would collect information from consumers and other stakeholders regarding feedback and notification of potential violations of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). Following the collection of these comments, the FDA will submit the Reporting Form to the Office of Management and Budget ("OMB") for approval. The request for comments and OMB approval are requirements under the Paperwork Reduction Act of 1995 ("PRA").

The request for comments seeks information on, among other things, "whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility," and "the quality, utility, and clarity of the information to be collected."[1] These questions

---

[1] 44 U.S.C. § 3506(c)(2)(A)(i) and (iii).

go to the core of three (3) of the most important purposes of the Paperwork Reduction Act of 1995 ("PRA"): to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government;" to "improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society;" and to "minimize the cost to the Federal Government of the creation, collection, maintenance, use, dissemination, and disposition of information."[2] Examining these principles, the FDA's proposed Reporting Form and program are problematic.

The proposed Reporting Form and program will not effectively further the functions of the agency, provide information that has much practical utility, nor ensure the quality of the information received. The ability of individuals to file anonymous reports creates a very real risk of abuse by competitors and other parties. Further, the form is not appropriately tailored to gather accurate information from the general public.

Concerns Regarding Anonymity

The FDA has removed any accountability on reporters to be truthful and factual with the agency by not requiring reporters to identify themselves. Subject to 18 U.S.C. § 1001, it is a federal crime to knowingly and willfully make a materially false, fictitious, or fraudulent statement or representation. Under the FDA's proposed Reporting Form, however, an individual would be able to make countless false reports to the FDA, without any recourse whatsoever.

Based on a review of the timeframes between the conclusion of retailer inspections and the issuance of Warning Letters, the agency can ill afford distractions from its compliance and enforcement work. Significant delays in the process already hamper a retailer's ability to confirm the occurrence of violations and develop a remedial plan. As of October 4, 2011, the average length of time between an inspection of a tobacco retail facility and the subsequent issuance of a Warning Letter was seventy (70) days. Figure 1 displays the minimum, maximum, and average number of days from inspection to Warning Letter, by state.[3]

---

2 44 U.S.C. § 3501.

3 Data was compiled as of October 4, 2011.

Retailer State	Number of Warning Letters	Days from Inspection to Letter - Maximum	- Minimum	- Average
AL	21	121	56	87
AR	26	104	28	78
AZ	34	98	14	55
CO	103	134	23	71
ID	1	18	18	18
IL	47	99	22	62
KS	8	115	65	97
MA	98	118	19	68
MD	22	121	15	75
ME	16	89	32	61
MO	87	122	23	81
MS	180	120	21	57
NJ	1	115	115	115
PA	71	115	37	96
TN	33	103	26	73
WA	89	114	28	63
All	837	134	14	70

Figure 1

This data is represented graphically in Figure 2.

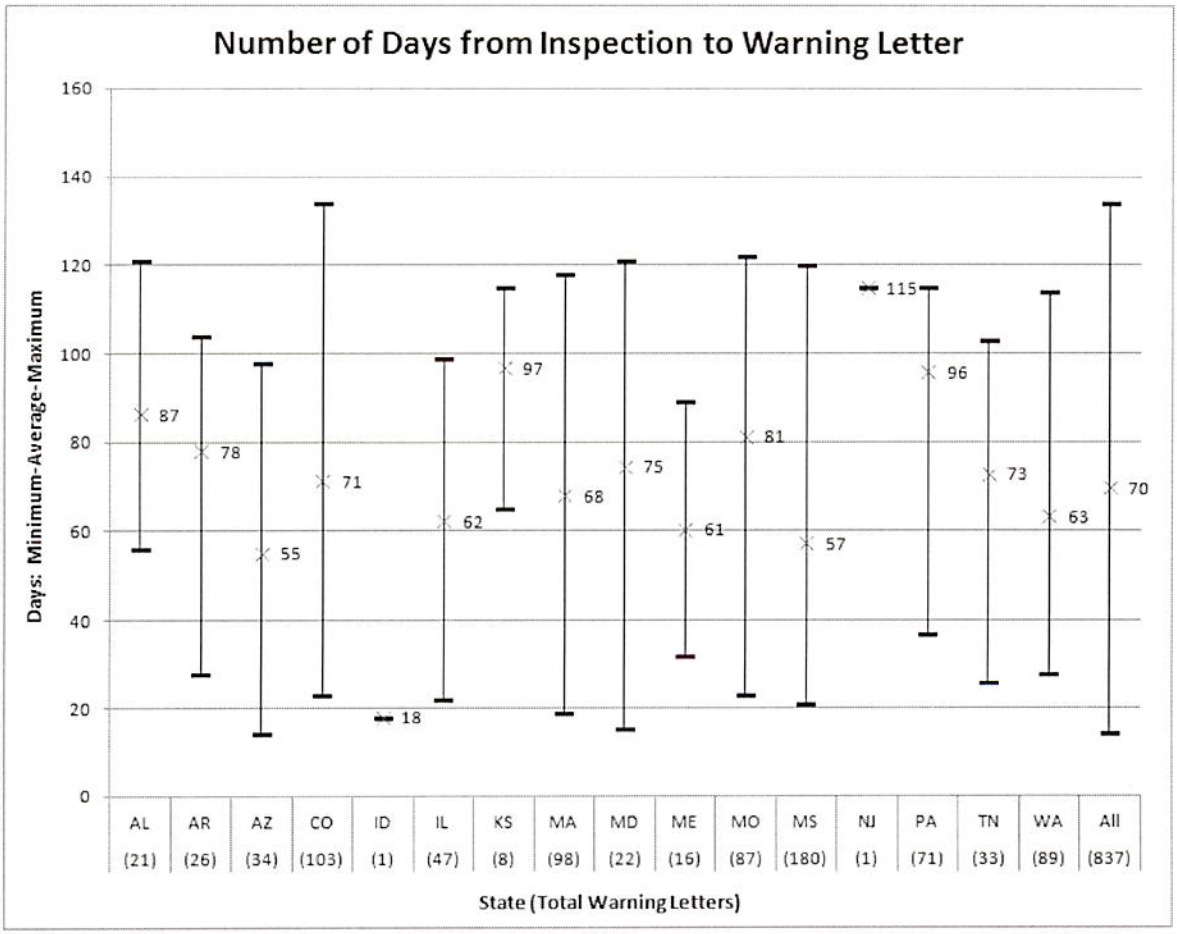


Figure 2

Dedicating FDA's already taxed resources to the process of chasing false or anonymous leads will further undermine its efficiency, and further extend the time required to issue Warning Letters. At a minimum, the Reporting Form should inform reporters that they are subject to criminal penalties under 18 U.S.C. § 1001 for making a materially false, fictitious, or fraudulent statement or representation.

Capability of the Public to Issue Meaningful Reports

While the FDA has previously developed public reporting programs, the Reporting Form at issue here stands alone in that FDA is soliciting participation from all members of the general public, regardless of whether they have specialized knowledge of the regulations applicable to tobacco retail establishments. For instance, FDA's "Bad Ad" program solicited reports from medical professionals of violative prescription drug advertisements. The

"Bad Ad" program targeted a specific cross-section of the general public because of that group's professional-level familiarity with the prescription drug industry. Even with that level of education, the "Bad Ad" program included an extensive educational program and outreach for medical professionals about the types of advertising they should look for. Conversely, the currently contemplated Reporting Form requires no such prerequisite professional qualifications of its submitters. The reports are solicited from and will be collected from an uninformed public and, as such, are far less likely to contain accurate information.

In fact, FDA Form 3779 is so vague as to virtually ensure inaccurate reporting. Despite soliciting information from an uninformed population with no specialized knowledge of tobacco regulations and enforcement, the Reporting Form does not even provide basic descriptions for what constitutes a violation. The main section of the Reporting Form presents a list of boxes a submitter can check off to describe a potential violation:

Potential violation type (choose all that apply)	☐ Sales to minors
	☐ Flavored cigarette sales
	☐ Advertising/promotion/marketing
	☐ Free samples
	☐ Vending machine/self-service display/direct access to cigarette or smokeless tobacco
	☐ Sale of cigarettes in packs less than 20
	☐ Other
Type of potentially violative promotional materials (choose all that apply)	☐ Newspaper
	☐ Magazine
	☐ Periodicals
	☐ Billboard
	☐ Direct Mail
	☐ In-store advertisements
	☐ Price signage
	☐ Posters
	☐ Coupons
	☐ Internet advertising
	☐ Other
Who potentially violated? (choose all that apply)	☐ Retailer
	☐ Manufacturer
	☐ Importer
	☐ Distributor
	☐ Other

The "Advertising/promotion/marketing" category is so broad it lacks any specificity whatsoever. Some members of the public may be inclined to identify any type of advertising as violative, based merely on their personal distaste for the product advertised. Further, this will surely result in a number of reports related to advertising violations under 21 C.F.R. 1140.32(a), despite the agency's decision to apply its enforcement discretion concerning this provision.[4] As there is no distinction between advertising violations and promotion or

---

[4] FDA, "Guidance for Industry and FDA Staff: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco," 75 Fed. Reg. 25,271 (May 7, 2010).

marketing violations, the agency may be inundated with reports that it will be unable to distinguish between appropriate violations and those not being enforced.

The boxes listed under "Types of potentially violative promotional materials" may further create confusion among the public. By their presentation on the Reporting Form, these boxes suggest that any type of promotional material falling into one of these categories is violative. For instance, it includes "Price Signage" as one type of potentially violative promotional material, but no explanation is given for what this might cover. While the FDA may not intend to imply that posting the price of a tobacco product constitutes a violation, an uninformed member of the public may certainly draw that inference. By failing to provide concrete definitions of each violation type with accompanying examples, the FDA has practically guaranteed that it will receive nothing but false and inaccurate reports.

Further, the Form FDA 3779 covers promotional materials not currently regulated by the FDA. Apart from the restrictions on advertising that have been stayed indefinitely by the FDA due to ongoing federal challenges of these regulations, we are unaware of the FDA making any policy or enforcement statement regarding advertising on the Internet. Based on statements made by the FDA in the preamble of the original Final Rule, the agency has stated that such advertising requires no prior approval. It is simply illogical to invite members of the public to report potential violations of these regulations after the FDA has announced that it will not enforce them.

* * * *

Smoker Friendly appreciates the opportunity to provide comments on enforcement matters impacting its members. We look forward to continuing to engage the agency on these matters in the future. If you have any questions concerning these comments, please contact me through the address, phone number, or e-mail address provided in the letterhead on the first page.

Sincerely,

Seth A. Mailhot

for SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

LEVIN GINSBURG

ATTORNEYS AT LAW

180 NORTH LASALLE STREET ▪ SUITE 3200
CHICAGO, ILLINOIS 60601-2800
312.368.0100

2011 OCT 26 A 11:00

October 21, 2011

Via Certified Mail, Return Receipt Requested and Email Transmission Via regulations.gov

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

RE: Comment Regarding Docket No. FDA-2011-N-0553 (Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Reporting Violation Form)

Dear Food and Drug Administration:

We are submitting these comments because we are a law firm that focuses a portion of our practice representing the interests of tobacco manufacturers, distributors and retailers. This comment addresses FDA's intent to collect specific information contained in a proposed tobacco product reporting violation form, no. 3779, which would replace the current form 3734 titled "Information Regarding Cigarettes With Characterizing Flavors." According to FDA, it is requesting Office of Management and Budget (OMB) approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (the "Act"). Part of FDA's related enforcement strategy is to accept information from the public about alleged violations of the Act and to allow callers to report potential violations of the Act so that FDA can conduct targeted follow up investigations based on information received. In order to expedite this reporting, FDA has developed a form that will be used to solicit this information from the caller (FDA Form 3779, Tobacco Product Violations Reporting), which is expected to replace current FDA Form 3734 for Cigarette Flavor Ban Violations. FDA wishes to post the new form on its website so that information may be submitted by the public by completing the form online. There are several comments we wish to make with respect to the notice. Certain of these comments echo the National Association of Tobacco Outlets' comments. Furthermore, the comments below set forth reasons why there should not be any reporting form posted by FDA, but that if one is posted, it should be the new Form 3779, with a few caveats.

First, the Act does not contain any requirement that FDA seek out or request comments from the general public regarding potential violations of the Act. Within the last several months, FDA has contracted with various state agencies to conduct inspections of retail premises and no doubt is expending great resources in doing so, making it unnecessary to request information from the

FDA-2011-N-0553

C

public regarding alleged violations. Furthermore, Illinois, where we are located, as well as most, if not all, States have city, county as well as statewide tobacco investigatory enforcement units which routinely enforce local ordinances and state law relating to tobacco, and can and do report to FDA. It is unlikely that any member of the public is as highly trained as an FDA investigator, or the various state agencies with which FDA has contracted, regarding the terms of the Act, how to conduct an inspection and how to recognize a potential violation. As a result, FDA could find itself dealing with inaccurate reports and reports which do not even address a violation of the Act but which FDA nonetheless has to spend time and taxpayer dollars reviewing. This type of permissiveness with respect to general reporting from the public can lead to anti-tobacco organizations filing unjustified and frivolous reports and industry competitors filing unjustified and frivolous reports against one another. This will result in low quality reports of very little, if any, value. Neither the proposed form 3779 nor current form 3734 requires that the report be filed under oath subject to penalty of perjury. Given the risks (detailed above) associated with allowing anybody to file a report, there should be some assurance that if form 3779 is approved that it will not be abused. The repercussions to businesses that are subject to false or unjustified reports can be severe, and there should be repercussions against the person filing false or unjustified and frivolous reports.

Form 3779 must also state very clearly at the top that possible violations are limited to only cigarettes, roll-your-own tobacco and smokeless tobacco and not any and all imaginable tobacco products. We understand that the fourth line of the proposed form stating "Description of Product Type" references: "cigarette, smokeless, roll-your-own, and other." We strongly suggest that the term "other" be removed because it leaves so much to the imagination and will not make any sense to the general public or even many trained investigators. For example, members of the public and even trained investigators may not be aware that FDA is not authorized to regulate pipe tobacco under the Act. Reports regarding pipe tobacco would result in a waste of time and resources. In addition, for clarification purposes the word "tobacco" should be added after "smokeless" and "roll-your-own."

In conclusion, it would be most appropriate for there to be no tobacco product reporting forms posted. If an interested consumer or stakeholder is truly interested in reporting a violation, it goes without saying that they can always contact or write to FDA. However, if a reporting form is to be posted, the new form 3779 is certainly an improvement over form 3734 which is woefully inadequate and insufficient, as it does not cover any potential violations but for those related to flavored cigarettes. If nothing else, form 3779 is preferable, but the product description section should only reference: "cigarettes, smokeless tobacco and roll-your-own tobacco."

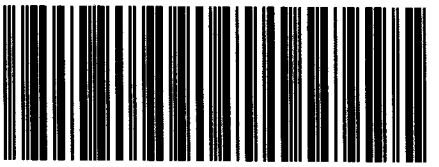
Should you have any questions with respect to the foregoing, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

JONATHAN M. WEIS
jweis@lgattorneys.com

JMW/dl

Jonathan M. Weis
Levin Ginsburg
180 North LaSalle Street
Suite 3200
Chicago, IL 60601



7196 9008 9040 0542 4819

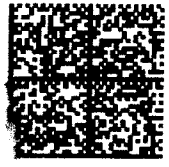
RETURN RECEIPT (ELECTRONIC)

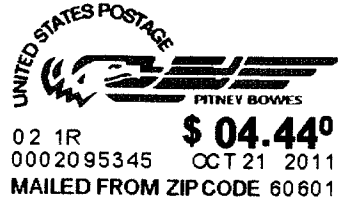
Division of Dockets
Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

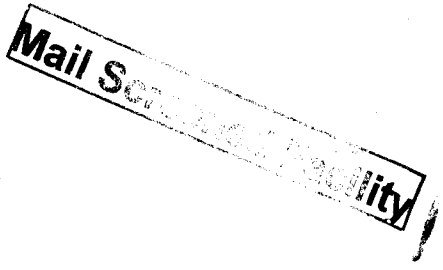
Total Postage: $ 4.44

Reference Number: 748801

CERTIFIED MAIL







OCT 25 2011

20857X0001