

CLARK-ESPOSITO

LAW FIRM, P.C.

LEGAL BULLETINS

2025

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From: Deanna Clark, Esq.

Date: January 10, 2025

Re: FDA Updates Import Alerts to Reinforce Detention of Unauthorized E-Cigarettes

Dear Valued Clients.

At the Clark-Esposito Law Firm, P.C., we are always working to keep you up to date on the latest legal and regulatory updates that may impact your business. Effective January 3, 2025, the U.S. Food and Drug Administration (FDA) announced updates to two import alerts: 98-07 and 98-06. These reinforce FDA's policies regarding unauthorized e-cigarette products and other tobacco products entering the United States.

Import Alert 98-07: Unauthorized E-Cigarette Products

FDA has strengthened its policies regarding unauthorized e-cigarette products to help prevent their importation into the United States. These changes provide additional clarity and resources for importers and federal enforcement agencies to identify and address unauthorized products. Key updates include:

- All unauthorized e-cigarette products may be detained without physical examination and refused admission by FDA.
- Links to FDA's Searchable Tobacco Products Database and a downloadable list of authorized e-cigarette products are now available for guidance.
- Pending applications do not provide a legal safe harbor for unauthorized products.

Import Alert 98-06: Other Tobacco Products

In addition to e-cigarettes, FDA has updated its import policies for other tobacco products, including smokeless tobacco and nicotine pouches. These updates aim to ensure that only authorized products enter the U.S. market. Key updates include:

- Focuses on smokeless tobacco and nicotine pouches, including NOIS, LYFT, and SKRUF brands.
- These products may also be detained without physical examination and refused admission by FDA.

Key Considerations

Compliance is critical to avoid penalties and enforcement actions. Ensure that all imported tobacco products have FDA authorization and that your operations align with federal regulations. Regularly consult FDA's Searchable Tobacco Products Database for the most up-to-date information on authorized products and guidance for importers.

Accurate and complete declarations are essential. Work closely with your trade partners, including customs brokers, to review and confirm that all information submitted to regulatory agencies is precise and adheres to FDA requirements. Taking these steps can help prevent costly delays or enforcement actions.

We are always here to help. Our team is available to provide guidance and support in navigating these regulatory updates and ensuring compliance. If you have any questions or need assistance developing effective compliance strategies, please don't hesitate to reach out to us. Your proactive approach to regulatory compliance helps protect your business and ensures smooth import operations.



Legal News Bulletin

New Mandatory Business Registration Impacting You

At the Clark-Esposito Law Firm, P.C., we are always striving to keep you informed regarding legal developments that may impact you and your business. Starting this year, there are significant changes to the *Beneficial Ownership Disclosure Rules* that carry significant penalties for failing to comply.



Mandatory 2024 Beneficial Ownership Filing Requirements

Unless it falls into an exception, all businesses are now mandated to file "beneficial ownership" information with the *Treasury Department's Financial Crimes Enforcement Network (FinCEN)*. Any existing company must file within 2024, while new companies started this year must file within 30 days of the entity being formed.

Key Considerations

- Penalty for not complying is \$500 per day for each day the violation continues
- Potential criminal penalties, including jail time up to 2 years and/or a \$10K fine
- The rule applies to corporations, LLCs, and other entities formed under state law
- "Beneficial Owner" is defined as any person who exercises substantial control over a company, or owning/controlling at least 25%

It is crucial to be aware of this change and what it entails. **Many small businesses may mistakenly believe that it does not apply to them because of their small size —but it does.** Larger companies are more likely to be exempt because this information has already been provided as part of their annual filing.

If you have any questions or need assistance, schedule an Introductory call with our office by calling us at (917) 546-6997, or email us at contact@clarkespositolaw.com.

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From: Deanna Clark, Esq.

Date: January 10, 2024

Re: Client Forwarded Emails and Document Submission Guidelines

Dear Valued Clients,

At the Clark-Esposito Law Firm, P.C., we are always working to improve our processes and enhance communication with you. Effective immediately, we are instituting the following process all clients are required to follow when forwarding emails, or submitting documents via email, to anyone at the firm.

Forwarded Emails and Their Corresponding Attachments

There are times where clients intend to forward emails received by clients from others, to our firm. In our experience, too often, those forwarded emails contain attachments which we are unable to open. To ensure our receipt of full communications from client-forwarded emails, we are instituting the following policy and procedure effective January 1, 2024. This will serve the purpose of both allowing us to obtain the full set of correspondence that you, the client, intend for us to receive. It will also reduce the amount of time staff will need to organize such materials and thereby reduce the charges incurred by you, regarding the same.

In cases where multiple email communications exist with attachments that will be provided to the firm, clients are required to compile each relevant email communication and their respective attachments into a single PDF document. That is, there should be a separate PDF for each email and its corresponding attachments. Clients should follow the following steps to ensure compliance:

- 1. Select and gather all relevant email communications and their attachments individually.
- 2. Separately merge each email with its attachments into a single PDF file.
- 3. Name the PDF document with the date and a brief description of the subject matter.
- 4. Send the complied PDF document as an attachment in one (1) or more emails to the firm.

Forwarded Documents

The document submission process is similar to the email communications and attachments submission process above, in that any documents submitted should be sent over in separate PDFs with their pages chronologically ordered.

This new document submission process is crucial for enhancing efficiency. By consolidating emails and attachments into organized PDFs, we save valuable time that would otherwise be spent sorting through disorganized files. This increased efficiency not only allows for us to focus more on providing you legal services, but also contributes to cost savings for you, our clients.

Your cooperation in adopting this streamlined approach is greatly appreciated. Where this process is not followed, we may either notify you of your need to organize your files in accordance with the above, or proceed with organizing the materials you have provided us with. Doing so will result in fees being incurred at our regular rates for work performed.



LAW FIRM, P.C.



The Clark-Esposito Law Firm, P.C. Difference

- Transforming Complexity into Clarity.
- Unwavering Professionalism and Commitment.
- Systematic and Responsive Case Management.
- Expertise in Inter-Agency Case Handling.
- Strategic Approach and Creative Solutions.
- Client-Centric Approach: Serving Only When We Can Truly Assist.
- Understand The Needs and Challenges of a Small Business.



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