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FDA Pending Regulation / OMB Meeting



In this report I will present the economic impact of the pending FDA regulations on Vanguard Distribution. It is in our opinion that the regulations as they stand now, will be too costly for the continuation of business. There are many financial road blocks that will affect the products that we distribute, copack, and manufacture. We supply 2,288 clients across the county, that resell our products. Some companies we represent could not begin to afford the Pre Market Tobacco Application. This in turn would deplete our offerings as well.

Manufactured Products:

Smoker Friendly, 75 SKU numbers
Screaming Eagle, 170 SKU numbers
Bayou Swamp Drops, 72 SKU numbers
Smoking Crow, 80 SKU numbers
Action Fluid, 72 SKU numbers
Nitemare Creations, 50 SKU numbers
Deep Blue, 60 SKU numbers
Exodus, 29 SKU numbers
Merkury, 36 SKU numbers



One product, one flavor, one nicotine strength including zero nicotine = \$2,000,000.00 PMTA

This category represents **644** individual SKU numbers. If you consider the amount of each PMTA to be **\$2,000,000.00**, the total that would have to be spent to put these products to market, will be **\$1,288,000,000.00**. This is before the product is made, bottled, distributed and sold to a customer for final sale.

Distributed Products

Jason's Juice Joint, 48 SKU numbers

Nevermore, 40 SKU numbers

Space Jam, 117 SKU numbers

ISM Vape, 60 SkU numbers

Vapor RX, 20 SKU numbers

Charlie's Chalk Dust, 70 SKU numbers

Treasure Island Elixir, 15 SKU numbers

Cutwood, 45 SKU numbers

Bamboo Elixir, 20 SKU numbers

Bushido, 12 SKU numbers

Beard Vape Co., 60 SKU numbers

Traditional Juice, 40 SKU numbers

Uncle Mike's Elixir, 16 SKU numbers

Fog Fluid, 24 SKU numbers

ReVol, 20 SKU numbers

Villain Vapor, 20 SKU Numbers







This category represents 652 individual SKU numbers. If you consider the amount of each PMTA to be \$2,000,000.00, the total that would have to be spent to put these products to market, will be \$1,304,000,000.00. This is before the product is made, bottled, distributed and sold to a customer for final sale.

OMB

Manufactured:

Distributed:

Result:

1,288,000,000.00 + 1,304,000,000.00 = 2,592,000,000.00 PMTA

Employees:

4 retail, and 22 in distribution and manufacturing

Total of 26

Suppliers:

We have 141 suppliers and have spent \$2,663,626.00 with them since 2014.

Customers / Sales:

We have approximately 2,288 wholesale customers since 2014, with an average sale of \$1,820.55 per client, based on total sales of \$4,165,419.00.

Retail customers would be approximately 4,619 serviced since 2014, at an average sale of \$188.00, based on a retail sales based of \$867,989.00.

Facilities:

Manufacturing and Distribution center 10,274 square feet, with ISO 7 cleanroom at 528 square feet.

Retail Location at 1,606 square feet

Closing:

Vanguard Manufacturing would like to propose that the OMB Push the deeming regulations back to the FDA asking them to design a modified PMTA that can be supported by small businesses. Furthermore initiate or support the efforts in congress to have the Grandfather date changed to the date the deeming regulations are introduced, allowing innovation already on the market to stay and enter through such modified PMTA. A modified PMTA that could be supported through small businesses could look something like a listing of approved ingredients in e-liquids based on current medical data already introduced. As we support regulation, over regulation will stifle small business growth and innovation.