

“To Free or Not to Free”

There is something rotten in the State of Denmark (a/k/a the FDA) but things are not quite as bad as they may have appeared to Hamlet when he gave his famous “to be or not to be” speech. Yes, there are many questions about what the FDA will and will not permit. And, unfortunately, the FDA does not always provide clear answers or, for that matter, any answers. Though what follows does not constitute legal advice, we wanted to try to bring some clarity to some important and practical issues based on our cumulative decades of FDA experience. Use this information as guideposts but, as always, please consult your own counsel to determine what your corporate policies should be and how to legally comply with the Deeming Regulation.

Compliance Pointers

- A penny per sample is not enough; whatever you charge, document how you calculated your fee.
- Provide your employees with clear written instructions on sampling.
- For sampling cards, make sure that you have a method for tracking to whom you sell the cards.
- Include clearly marked “SAMPLES” line item in your POS system and on receipts; charge applicable tax.
- You may offer coupons or Buy One Get One sales.

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ALL ABOUT CUSTOMER SAMPLING

WHAT IS A SAMPLE?

The short answer: Consumption of a vapor product.

The better answer: Any amount of consumption is considered a sample. People

may have different opinions on what constitutes a sample or what it really takes for anyone to properly “sample” a flavor or product. Those **opinions are irrelevant.** The short answer above is what is relevant.

WHAT IS A FREE SAMPLE?

The short answer: Any sample for which the customer does not pay.

The better answer: A sample for which the customer pays nothing or pays a negligible amount.

It is important to note that, according to the FDA, it is not considered a free sample if a prospective buyer touches, holds, or smells a vapor product.

MAY I PROVIDE FREE SAMPLES TO MY CUSTOMERS?

The short answer: No.

The better answer: No. Never again. If you are doing it, STOP. If you see another retailer doing it, tell them to STOP.

HOW MUCH SHOULD I CHARGE FOR A SAMPLE?



The short answer: More than a penny.

The better answer: There is not one right answer to this question. Some have elected to charge per puff or per sample; others charge a fee for testing a given flavor up to a certain amount of puffs. Ideally, the amount you choose to charge will bear some relationship to the value of the sample offered, but it cannot be negligible. (See insert at page 4.)

Compliance Pointer

No fee is required for touching, holding, or smelling a vapor product

MAY I USE SAMPLING CARDS?

The short answer: Yes.

The better answer: The manner in which you collect money for samples is not dictated by the FDA. So, whether you charge a nickel or a dime,

you could sell sampling punch cards (i.e., 10 samples per card) so you do not have to ring up every small transaction. You would then punch the card each time the person takes a sample.



If you use sampling cards, we would recommend that you write the name of the customer on the back of the card. That way, you will know that the person using the card actually purchased the card. Since you should be asking every customer for identification, this will also tell you whether the person presenting the sampling card is the person who purchased it.

IF SOMEONE FROM FDA TELLS ME THAT 1 PENNY IS ENOUGH, MAY I RELY ON THAT?

The short answer: No.

The better answer: At this juncture, we are not aware of anyone in any position of authority at the FDA making any statement that one penny per sample is sufficient. Also, there is nothing contained in FDA guidance on the subject.

Some have commented that the FDA has answered questions by stating that one penny per sample is sufficient. However, relying on an FDA employee's unofficial oral statements interpreting the Deeming Regulation is very risky. Nothing would bind the FDA to such a statement or prevent it from "changing its mind".

Hence, we do not think that it is advisable for any retailer to charge only a penny per sample.

DISCLAIMER: The information contained herein is provided for general educational purposes only. It is not intended to provide, nor can it be relied upon, as legal advice or analysis. This Guidance is not a complete representation of compliance issues related to federal law. FDA application of the law as it relates to these issues may change. Companies affected by the Deeming Regulation should consult their lawyers with any specific questions related to compliance.

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Our thinking may change if and when the FDA provides clear written guidance, or if someone in a position of authority makes a declarative public statement on the subject. But, until then, we think that it is too risky to rely on any such unofficial statement.

SHOULD I TRACK OR RECORD MY SALE OF SAMPLES?

The short answer: Yes.

The better answer: You need to be able to demonstrate to the FDA that you charge for every sample that you provide.



Our suggestion is that you make certain to include a line item on your POS system for “SAMPLES” and/or “SAMPLE CARD” or something that accurately reflects the manner in which you are charging for samples. That way, each time you ring up a sample transaction that data is recorded in your POS system which you could use to show the FDA that you in fact routinely charge for samples.

Also, a line item or line items should be included on the customer receipt, again to demonstrate that you routinely charge for samples and to **make sure that you pay the proper sales tax on samples.**

COUPONS, SALES AND RAFFLES

MAY WE USE COUPONS OR RUN A LOYALTY PROGRAM?

The short answer: Yes.

The better answer: The FDA allows for the use of coupons so long as the redemption value of

the coupons are not for the full price of the vapor product. Additionally, the FDA allows businesses to offer loyalty programs for vapor products based on proofs-of-purchase.

MAY I ADVERTISE PRODUCTS AS BEING “ON SALE” OR RUN A BOGO PROMOTION?

The short answer: Yes.

The better answer: Nothing in the Deeming Regulation or the Tobacco Control Act prevents you from putting your products on sale or advertising that your products are on sale. Moreover, the FDA allows the promotion of your products in a Buy One, Get One Free (BOGO) or comparable manner.

MAY I OPERATE A RAFFLE?

The short answer: Yes.

The better answer: The question is and will always be, did you receive payment for the product that is raffled off. Remember, the payment must not be negligible and must bear some rational relationship to what is being offered.

MAY I INCLUDE SAMPLES AS PART OF A MEMBERSHIP CLUB FEE?

The short answer: Maybe, but it is too risky.

The better answer: The problem with including samples as benefit of any membership club is that you will have great difficulty in tracking and being able to explain how and how much you charged for each sample. At some point, a customer could misuse the membership

program to such a degree that the price per sample could be reduced to almost zero. We recommend steering away from this concept.

B2B SAMPLING

MAY A MANUFACTURER PROVIDE FREE SAMPLES TO DISTRIBUTORS OR RETAILERS?

The short answer: Probably yes.

The better answer: The FDA has not taken an explicit position on B2B sampling, and the free sampling provision does not specify whether it refers only to consumers. All discussion of free sampling in the Deeming Regulation, however, relates solely to providing free samples to consumers. The FDA has attended numerous tradeshows at which businesses have provided free samples to other businesses, and the FDA has taken no action.

It is worth noting that the larger cigarette companies have taken a very narrow view on this issue and no longer provide any free samples of their products to either their wholesale or retail partners.

Finally, the free sampling provision does not bar a regulated entity from providing samples at no cost to research institutions or testing labs.



If you are going to provide free samples to your wholesale or retail partners, you should consider taking additional precautionary steps such as:

(1) labeling the bottles as “NOT FOR SALE OR RE-SALE,” “NOT FOR CONSUMER USE,” “FOR B2B MARKETING ONLY” or something comparable that demonstrates the product is not and never was intended for purchase by consumers; and

(2) make clear in your transmission document or bill of lading that the free samples being provided may not be given to any consumer, may not be sold, and are being provided solely for B2B marketing purpose.

Customer Sampling Fee Models

Retailers have taken different approaches to customer sampling. Here are three examples.

Example 1: Pay per sample: Some are choosing to charge a flat nickel or dime for each sample (i.e., puff). Simple and easy to implement.

Example 2: Flavor sampling fee: Some have calculated the cost of 2 drops of flavor and determined how many puffs it takes to consume 2 drops. They charge flat fee for the 2 drop sample, knowing what the “per puff” cost amounts to, whether or not the customer uses all of the “puffs”.

Example 3: Taste Test fee: Some charge one price for 3 puffs (i.e., enough puffs to properly sample the flavor). While similar to Example 2, they limit the taste test to 3 puffs. They established what their cost is and then, including tax, end up charging a quarter (\$0.25) per taste test.