Dietary Supplement Q's

- Based on that definition, how do cannabinoids meet or fail that definition?

Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

- Can you address dietary supplements, such as tinctures, that have sublingual instructions? We are seeing a lot of processors wanting to put this on their label, but it does not fit the "dietary supplement" definition.

Sublingual consumption does not meet the criteria of ingestion, as the purpose is to cross the blood barrier and have the product enter the blood stream. For a product to be a supplement it must be ingested, sublingual consumption is only allowed in drug products.

- How do supplements fit with the additives within the retail food regs? We are seeing many "additives" in coffees/smoothies, etc.

Supplement ingredients do not have to follow food regulations such as being GRAS compliant. Dietary ingredients either a) must have been used in a supplement within the US prior to 10/15/1994, or 2) go through the New Dietary Ingredient Notification Process and FDA must conclude that they do not have any objections to the ingredient being used. However, each company that wishes to use this ingredient must file their OWN NDIN, they cannot rely on another firms application.

- Why is it allowed to be labeled a supplement fact on a drug for B12?

Vitamin B12 is sold both as a supplement and as a drug, the same is true for vitamins and minerals such as iron salts. To be a supplement ingredient, ingredients must have been sold as a supplement within the US prior to 10/15/1994, Vitamin B12 is widely accepted as meeting this criteria. To be classified as a supplement however, the product must be ingested and cannot be consumed sublingually or through an IV.

- Where does elderberry syrup fall? It is marketed as supplement but it may not be ingested right away, but puts into beverage for benefits

Elderberry is widely accepted as meeting the DSHEA requirements to be a dietary ingredient. If Elderberry meets GRAS standards then it can also be used in foods. The only difference between the two products would then be how the firm chooses to label the product, as a food or as a supplement.

- So will they use "herbal" as a ploy for consumers to bypass being inspected?

If the product is only labeled as an “herbal” on the PDP and is also accompanied by a Nutrition Facts Panel, then the firm would be allowed to sell the product as a food as long as all ingredients met GRAS requirements. If the label states “supplement” anywhere or is accompanied by a Supplement Facts Panel then we would consider it a dietary supplement.

- What regulatory authority does the FDA have over dietary supplements given that they don't face the same scrutiny and approval process as drugs?

Dietary supplements have the same CGMP requirements for manufacturing as a general foods, however, supplements are also required.to establish specifications for identity, purity, strength, composition, and limits on contamination. These specifications must be confirmed through testing or examination of the dietary ingredients, in-process products, packaging, labeling, and finished products. There is also a stronger emphasis on the quality control unit within supplements as QC must routinely sign off on written procedures, specifications, testing, failures to meet specifications or manufacturing requirements, and QC is the last line of defense at the firm that ensures the finished product is not misbranded or adulterated. Within supplements there is more of an emphasis on misbranding and ensuring that when the consumer purchases a product, they receive exactly what is listed within the Supplement Facts Panel.

- What about Kava bars? They are adding Kava to drinks.

Kava is allowed as a dietary ingredient in dietary supplements as it was used in the US as a supplement prior to 10/15/1994 and is therefore grandfathered in pre-DSHEA, however, it does not meet GRAS standards and cannot be used in food products with a nutrition facts panel. Post-market Determinations that the Use of a Substance is not GRAS

- If you put a tincture that is listed at a dietary supplement in a drink at home is it a dietary supplement?

If the tincture being sold to the consumer is labeled as a dietary supplement, then the product is a dietary supplement regardless of how it's being used by the consumer. The product instructions must state to ingest the product. If the product instructions say to put the tincture into a beverage at home and then drink that beverage, and the tincture bottle has supplement labeling and dietary ingredients, then it would be considered a supplement.

- If CBD is not permitted to be added to a supplement, how are national retailers such as GNC and Vitamin Shoppe selling CBD supplements?

It is not legal to sell CBD as a supplement, however, currently the FDA does not have a framework to inspect these products so none of them are being inspected by the federal agency. As CBD is legal in many states, however, this means that CBD is currently falling into a grey area where the FDA is not able to take action against these products. https://www.fda.gov/media/131878/download?attachment

- Can you tell me about Kratom and is it legal to sale?

Kratom is not appropriate for use as a dietary supplement. FDA has concluded from available information, including scientific data, that kratom is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury and, therefore, dietary supplements that are or contain kratom are adulterated.
FDA and Kratom | FDA

- What about the colostrum that is out there and all the rage?

Colostrum is a grandfathered dietary ingredient pre-DSHEA and is therefore allowed to be utilized in supplements.

- What's the difference between a nutraceutical and a supplement?

Within the US there is usually no difference, they are synonyms. However, each country uses different terms to describe supplements. Within the US we say dietary supplements, in Canada they say natural health products, in Australia they say complimentary medicines, in the EU they say food supplements.

- Can kratom be a supplement?

From the Federal standpoint, kratom is not lawfully marketed in the U.S. as a drug product, a dietary supplement, or a food additive in conventional food.

- Is a cliff bar a food or dietary supplement?

Cliff bars have a nutrition facts panel and market themselves as a food so we would consider them a food and not a supplement.

- Ultimate Magnesium creamsicle? It's sold by Force Factor. It supposed to calm and relax, stress relief, positive food. What is your personal opinion.

I love giving my personal opinion on supplements even if it has no impact on what we as a Federal Agency can enforce… First, I should say that I do not take ANY dietary supplements, sometimes you just get to a point where you see too much man. Force Factor Ultimate Magnesium, structure function claims include “support calm and relaxation”, “relieve stress”, “improve mood”. Are they allowable labeling statements, yes, would I believe them, probably not.

- Would bee pollen added to a smoothie in a smoothie shop be a supplement or a food?

Bee Pollen is a grandfathered dietary ingredient pre-DSHEA and is therefore allowed to be utilized in supplements. I am unaware of a GRAS notification for food additives, however.

- Is my herb store or shake shop safe if they do not make a statement on the label but instead have a library in a separate area (say at the register as or you walk in) that lists all the benefits of the ingredients?

Unfortunately, I do not have information on retail labeling requirements as they would be unique to your state.

- What about a claim of..."supporting your immune system" or similar? What is that considered?

This would be considered a structure function claim as it is a general wellbeing statement as defined in DSHEA. It is not stating that there is anything wrong with your immune system, but that your immune system is functioning as it is supposed to and the supplement is just supporting you in this.

- As a health inspector, I encounter OTC "supplements" imported from other countries, who regulates these products? They may or may not be labeled in English.

Imported products do need to have English labeling, however, the sheer volume of imports makes it impossible to review every entry that comes into the US. There is no definition for an OTC supplement in the US regulations, only OTC drugs and dietary supplements. Any product that is attempting to be both a drug and supplement is a misbranded product.

- Can you give an example of dirt water?

Without outing certain companies, I would encourage you to Google humic dietary supplements, fulvic acid dietary supplements or humate dietary supplement liquid to see examples of these products.

- Why can't sea moss be sold as a food?

Sea moss (commonly called Irish Moss) is a grandfathered dietary ingredient pre-DSHEA and is therefore allowed to be utilized in supplements. I am unaware of a GRAS notification for Sea Moss as a food additive however, and it does not appear in the SCOGS Database or the GRAS Notice Inventory.
Generally Recognized as Safe (GRAS) | FDA

- Can supplements be added to foods in restaurants?

If the dietary supplement meets GRAS requirements and is allowable as a food ingredient then this is allowable, however, this will depend on the state and local jurisdiction.

- For the cold/flu example, is there a difference in structure/function vs drug/disease claim between: "Support immune system during winter season" (implies the cold/flu season) versus simply "supports a healthy immune system."

There would not be a difference between those two statements as they would both qualify as structure function claims. They are not implying that there is something abnormal or unhealthy about the body or the immune system/immune response.

- Is there a list for approved food additives?

Food additives, you can go to the GRAS website on FDA.org Generally Recognized as Safe (GRAS) | FDA and find resources such as the SCOGS Database and the GRAS Notice Inventory. If a post-market determination was made by FDA about the ingredient and it was determined to not meet GRAS requirements you can find that list here Post-market Determinations that the Use of a Substance is not GRAS. As for dietary ingredients, there is no comprehensive list of allowable ingredients, however, certain trade associations do have internal lists that they have collected historical information on. The Office of Dietary Supplement Programs does have a website for dietary ingredient information which they have issued public statements on or taken regulatory action on but this list is far from being all-inclusive. Information on Select Dietary Supplement Ingredients and Other Substances | FDA

- Why has the FDA been evaluating vitamins for what seems like the 80's, but approves other supplements or even drugs in a matter of a year or less?

The requirements for drug evaluations is extremely detailed and well established while the process for evaluating the safety of supplements is not so. In addition, supplements

do not have to prove that they are safe and effective. Supplements must not be adulterated or misbranded but there are a variety of ways that the industry can produce these products. There is also no pre-market approval process for supplements, as long as you use either grandfathered pre-DSHEA ingredients or file a New Dietary Ingredient Notification and the Agency does not object, you can sell the product. In addition, structure function claims do not have to be substantiated, the way DSHEA was written, it puts the power in the hands of industry to say whatever they want as long as they phrase their labeling statements as structure function claims.

- Structure/Function vs Disease: How would statements like "helps with constipation" or "aids in reducing nasal inflammation" be covered?

“Helps with constipation”, as it is a normal and healthy function of the body to occasionally have constipation this would be considered a structure function claim. If the constipation was related to a health condition in the labeling such as, “Helps with constipation for those that suffer from Crohn’s” it would cross into the drug/disease category.

“Aids in reducing nasal inflammation”, inflammation while a normal function of the body is not a healthy state of the body so this would be considered a drug/disease claim. If the claim stated nasal irritation instead of inflammation, then this could be considered a structure function claim as it is normal and healthy to occasionally have irritation. Did you get sucker punched coming out of the grocery store last night? You probably have some natural nasal irritation. Did you breathe in some of your cat/dog/guinea pig/ferret fur, you probably have some irritation. For a claim to be considered structure function it has to both be the normal AND healthy state of the body.

- Are supplements manufacturers allowed to label their item with the "Nutritional Facts" panel? We see protein powders that are labeled as such in food service establishments and it would be good to know if we can regard those with said panel on the package as GRAS or acceptable to be used in food service.

If the protein powder labeled as a food meets GRAS requirements for its individual ingredients it is allowable. However, this means that the marketing for the product must be as a food and not as a supplement.

- Re: 'disease claims': Pharmaceuticals have many side affects as we all can agree. Do you think there will come a time when FDA will accept reviews from the many studies that reveal herbs, spices, (super foods) that have benefited certain health conditions and, thus, encourage this as a way to maintain health. What is hindering the backing of these studies.

Right now there is nothing stopping a dietary supplement from moving into the drug space and showing through clinical research that it can be used like a drug. A great example of this is Senna Leaf. You can purchase this product as a dietary supplement or as an OTC drug (Senna glycoside laxative OTC tablets). It is allowable as a

supplement because it was used as a supplement in the US prior to 10/15/1994 but it also went through the OTC evaluation process to be used as a drug. There is nothing stopping any supplement from going through this process, but it is an expensive evaluation for a marketplace and consumer base that would treat it the same whether it was sold as an OTC drug or a supplement. I do not see this changing in the future.

- Who regulates items that are topical but labeled as supplements? Are these items misbranded?

The FDA regulates cosmetics in certain situations, but it is much more fewer and far between than our regulation of foods or supplements. If the product uses ingredients that cross interstate lines or was sold to a customer and crossed interstate lines, and it is sold wholesale, then it would fall under FDA jurisdiction. If neither of these requirements are met, then it would not be federally regulated and would fall on the responsibility of state jurisdiction.