Hemp Products and Hemp By-Products In Food

1) Background:

Two major by-products in hemp are cannabidiol (CBD) and tetrahydrocannabinol (THC). Both of these compounds are considered controlled substances by Drug Enforcement Agency (DEA) and adulterants in both conventional food and dietary supplements by the FDA. CBD is also considered to be a drug by the FDA.

CBD and THC can be present in trace amounts in hemp products (such as hemp seeds and hempseed oil). Hence, food products, including hemp seeds and hempseed oil, containing these compounds would be considered adulterated. However, it is the Department's position that no enforcement action would be taken against hemp products with no amount or only trace amounts of CBD. Independent GRAS determinations of industrial hemp seeds and oil from these seeds have resulted in no objection from the FDA as long as only trace amounts of THC and CBD that resulted from crossover contamination during processing are present. Industrial hemp, by definition, should have less than 0.3% of THC on a dry weight basis. The Department has been unable to find research that suggests trace amounts of naturally occurring CBD and THC in hemp product poses a risk to public health. Hemp seed and hempseed oil products that have enhanced levels of these compounds would be subject to enforcement action.

2) Food Products containing Hemp Products or Hemp By-Products are noted during an inspection:

a) The product is or contains Hemp or Hemp By-Products including Hemp Seed or Hemp Seed Oil; and
    1. There is ***no*** statement on the label, in the ingredient statement or on any material that would be considered labeling (company advertising or website) stating the product contains phytocannabinoids, CBD or THC. The program will currently not take any action on this product.
    2. There is a statement on the label, in the ingredient statement, or any other material indicating that the products contains phytocannabinoids, CBD or THC. The program will take action on this product.

If you find products that are described in a. above, contact your manager or their designee during the inspection regarding the issue.

b) For products described in a. above, the potential actions to be taken by the Department include:

1. The firm voluntarily sending the product back to the manufacturer/supplier.
    a. Detain the product and make program notifications. Make sure you detail in the detention notification that the company wants to ship the product back to the manufacturer.
2. The firm voluntarily agrees to destroy the product
3. Company does not have a solution and does not want to destroy it:
    a. Detain the product and make program notifications.
    b. Follow regular detention procedures.

c) Firm Return of Product to Manufacturer/Supplier
1. If the firm requests to return the product to the Manufacturer/Supplier:
    a. PSQA will send the show cause letters
    b. PSQA will contact the state regulatory program where the product is to be shipped to determine if the program is concerned about the product entering commerce in their state and if they are willing to receive the product, release the detention, and notify the department of the arrival.
    c. PSQA will coordinate with Surveillance (as appropriate) to witness the shipment of the product under detention. If the state program declines to handle the process as stated in b. above, the detention of the product should be released before shipping and other methods for ensuring the product has been shipped to the manufacturer will need to be employed i.e. shipping receipt, etc.

d) All Other Detentions
1. In order to allow any product to be released into Commerce (other than as described in 3a above)
    a. PSQA will request laboratory analysis from the firm.
        1. The analysis must be from an accredited laboratory
        2. The analysis must show levels of CBD and THC
    b. If the results show only trace levels of CBD or THC, the product can be released. PSQA will notify Surveillance the product may be released.
    c. If the results show elevated levels, PSQA the notifies the firm and Surveillance of the findings. The firm will need to destroy the product or contact PSQA for other options.