Cartoon of Skeleton Serving a Tray of Poisonous Food Additives in the early 20th century. Image from the Food & Drug Administration

FOOD ADDITIVES:
HISTORY & APPROVAL

Washington State Department of Health

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Truth in Advertising: Presentation Objectives

1. **Brief Summary of Food Additive Laws and Regulations**
   History has taught lessons
2. **Food Additive Approval Process in United States**
   Understand the process to have additives approved
3. **Recent Changes with Cannabis**
   Be aware of key national and state changes
4. **Moving Forward**
   Understand roles of food safety with emerging business models and changing laws

What is a Food Additive?

"Any substance the intended use of which results or may reasonably be expected to result -- directly or indirectly -- in its becoming a component or otherwise affecting the characteristics of any food."

- This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food
- The definition excludes ingredients whose use is generally recognized as safe

03315 Preventing food and ingredient contamination--Protection from unapproved additives (2009 FDA Food Code 3-302.14).

(1) FOOD must be protected from contamination that might result from the addition of, as specified under 03240:

(a) FOOD ADDITIVES or COLOR ADDITIVES that are unsafe or not APPROVED; and

(b) Unsafe or unapproved levels of APPROVED FOOD ADDITIVES and COLOR ADDITIVES.

1906 Food & Drug Act

- Dr. Harvey Wiley

  Hygienic Table Studies
- "Truth in Labeling"
  - The basis of the law rested on the regulation of product labeling rather than pre-market approval
- Gould Amendment (1913) required contents be plainly marked on the outside of the food package

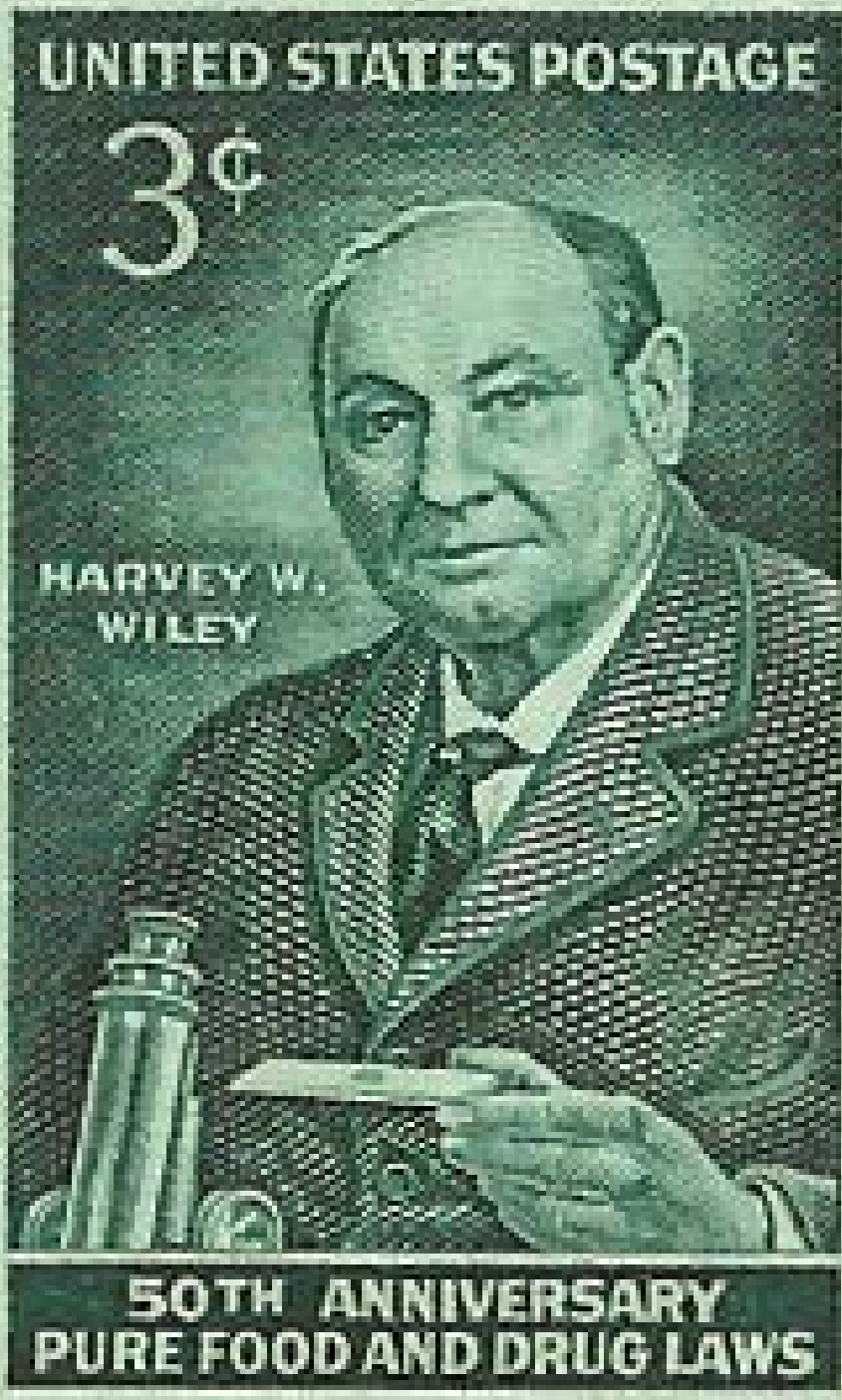


Image of postage stamp of Harvey W. Wiley - June 27, 1956 Commemorative 50th Anniversary of Pure Food and Drugs Laws Designer: Robert Miller - Engraver: C. A. Brooks

1938 Federal Food, Drug, and Cosmetic Act

- Elixir Sulfanilamide
- Franklin Delano Roosevelt signed the act on 6/25/1938
- The first food standards to be issued were for canned tomato products

Photo of Elixir Sulfanilamide bottles, circa 1937-1938
Author Unknown, Photo Public Domain

Amendments to FD&C Act

1958 Food Additives

- All additives need advanced approval with two exemptions:
  - GROUP I - Prior-sanctioned substances that FDA or USDA had determined safe for use in food prior to the 1958 amendment
  - GROUP II - GRAS ingredients that are generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence
- "Delaney clause" provision carcinogenic substances may not be used as a food additive

1960 Color Additives

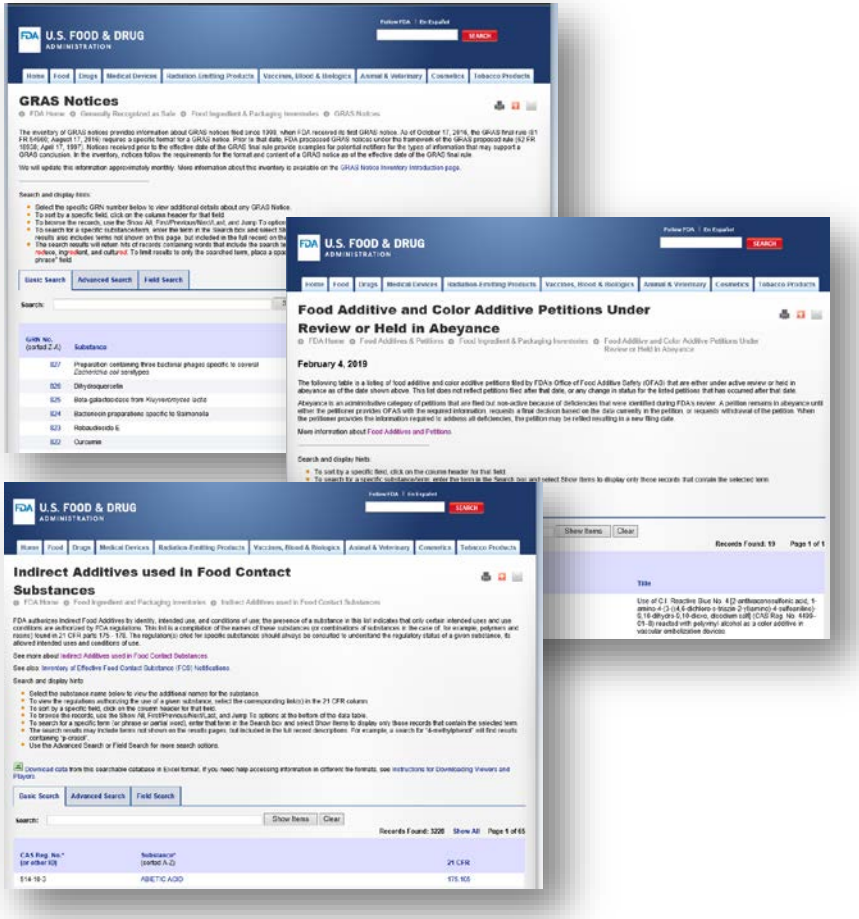
- Required manufacturers to establish the safety of color additives prior to use
- About 200 color additives were in use.
- Color additives are not listed as GRAS
  - **Certified colors** are synthetically produced, impart an intense, uniform color, are less expensive, and blend more easily to create a variety of hues. There are nine certified color additives approved for use in the United States.
  - Colors that are **exempt from certification** include pigments derived from natural sources such as vegetables, minerals or animals.

Generally Recognized As Safe (GRAS)

- Companies may voluntarily notify FDA that a particular use of a substance is determined to be GRAS
  - FDA will make an evaluation and provide a written response
  - FDA response will
    - not question the basis for the notifier's GRAS determination
    - determine that the notice does not provide sufficient evidence for the notifier's GRAS determination, or
    - cease to evaluate the GRAS notice per the notifier's request

FDA Resources for Food Additives

1. Food Additive Status List
2. GRAS Notices
3. Substances Added to Food Database
4. Indirect Additives used in Food Contact Substances
5. Food Additive and Color Additive Petitions



Three FDA website screenshots on food additives

Cannabis

- Cannabis contains more than eighty biologically active chemical compounds.
- The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).
- Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act since 1970.
    - High potential for abuse (attributable to the psychoactive effects of THC)
    - Absence of a currently accepted medical use of the plant in the United States.

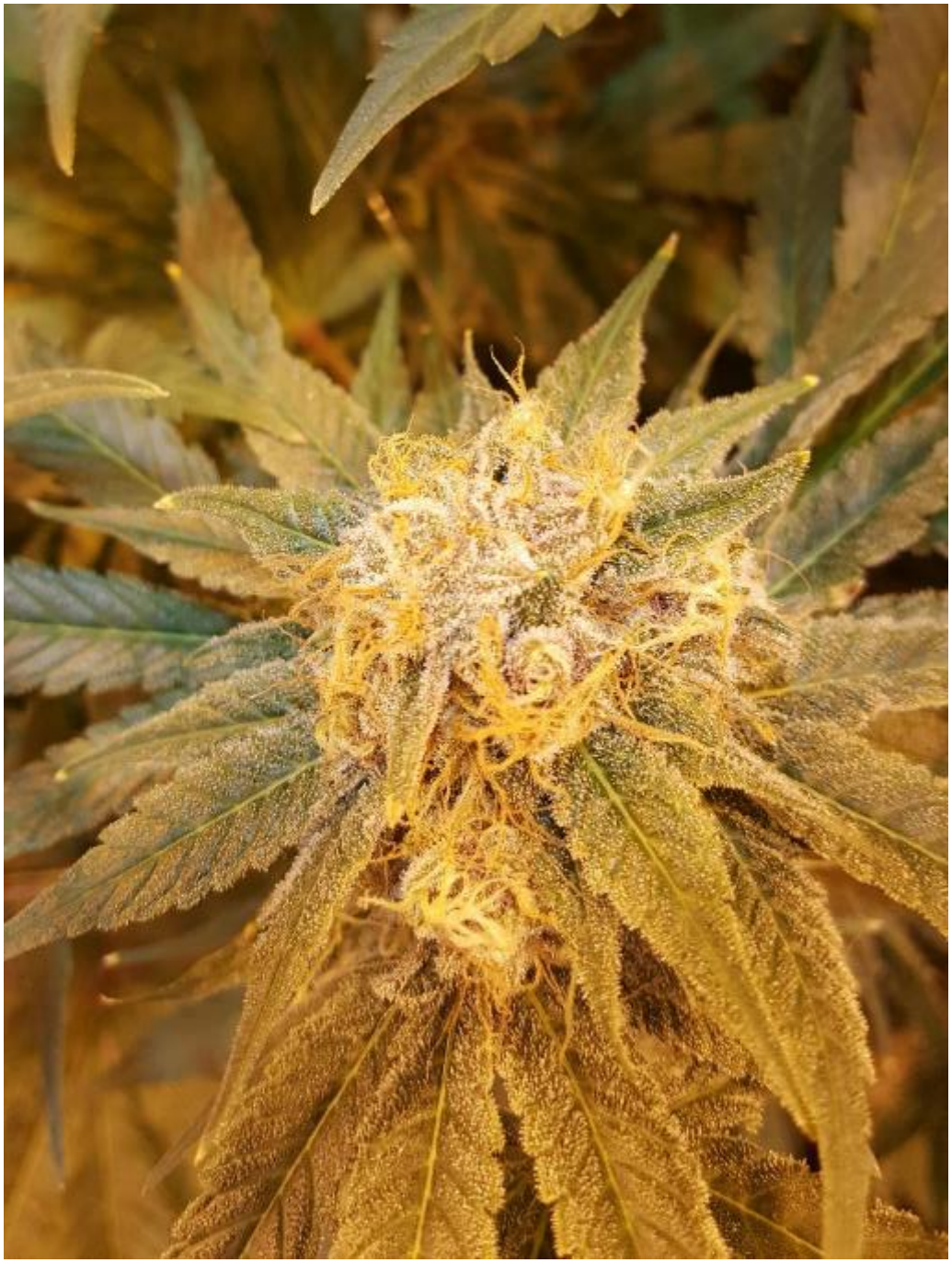


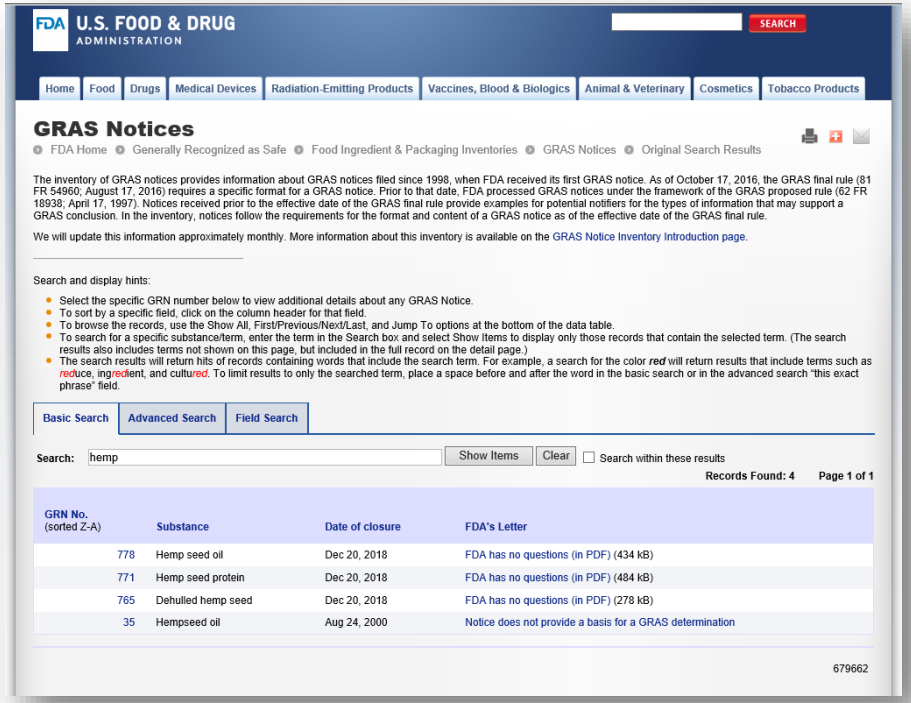
Photo of Cannabis plant highlighting trichomes, Photo Taken by Susan Shelton

CBD as a Drug

- Under the FD&C Act, any product intended to have a therapeutic or medical use is a drug.
- Any product that is intended to affect the structure or function of the body of humans or animals, is a drug. (Not including food)
- Prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act

Hemp Seed & Hemp Seed Oil

- In December 2018, FDA completed evaluation of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients:
  - hulled hemp seed
  - hemp seed protein powder
  - hemp seed oil
- These products may be legally marketed in human foods



Three FDA website screenshots on food additives

2018 Federal Farm Bill

- Agriculture Improvement Act of 2018 signed into law on Dec. 20, 2018
- Removed hemp from the Controlled Substances Act
  - Cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.
- Explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act
- FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products

Engrossed 2nd Substitute - E2SSB 5276

- Signed and effective 4/26/19
- "Hemp" means any part of the *Cannabis sativa L.* plant with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis
  - includes seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not
- The whole hemp plant may be used as food.
- WSDA shall regulate the processing of hemp for food products, **that are allowable under federal law**, in the same manner as other food processing under chapters 15.130 and 69.07 RCW and may adopt rules as necessary to properly regulate the processing of hemp for food

Moving Forward

- Long history in food additives and regulations implemented after illness or injury
- CBD is not a federally-approved food additive in the United States for retail food
- FDA will be hosting a listening session on 5/31/19 on the addition of CBD in retail food
- CBD is not a state-approved food additive for retail food until federally approved
- CBD is allowed as an edibles ingredient in facilities licensed by Washington State Liquor Cannabis Board

Thank you.

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