Who are the FDA?

The **Food and Drug Administration, FDA**, is an agency of the United States Department of Health and Human Services and is responsible for the safety regulation of most types of foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics. The FDA also enforces parts of the US Public Health Service Act and the associated regulations.

What are their origins?

Up until the 20th century, there were few federal laws regulating the contents and sale of domestically produced food and pharmaceuticals. The history of the FDA can be traced to the latter part of the 19th century and the U.S. Department of Agriculture's Bureau of Chemistry. In 1883, the Division began conducting research into the adulteration and misbranding of food and drugs on the American market. Although they had no regulatory powers, the Division published its findings from 1887 to 1902 in a ten-part series entitled *Foods and Food Adulterants*.

Then in June 1906, President Roosevelt brought in the Food and Drug Act. This prohibited the transport of food which had been "adulterated", ie the addition of fillers of reduced "quality", colouring to conceal "damage or inferiority", formulation with additives "injurious to health" or the use of "filthy, decomposed or putrid" substances.

In 1927, the Bureau of Chemistry's regulatory powers were reorganized under a new USDA body, the Food, Drug and Insecticide organization. This name was shortened to the **Food and Drug Administration (FDA)** three years later.

A new law, established in 1938, significantly increased federal regulatory authority and expanded enforcement powers, set new regulatory standards for foods and cosmetics under federal regulatory authority. This law, though extensively amended in subsequent years, remains the central foundation of FDA regulatory authority today.

What are FDA regulations for high quality oils?

Within the white oil and lubricants industries, FDA regulations are often quoted in short form such as FDA 178.3620(a) White Mineral oil or FDA 178.3620(b) Technical White oil. These are summaries of complicated FDA descriptions for oils acceptable for medicinal white oil and technical white oil applications. The full classification is as follows!

“FDA **C**ode of **F**ederal **R**egulations Title **21**--Food & Drugs; Chapter I --Food & Drug Administration; Department of Health & Human Services; Subchapter B -- Food for Human Consumption; **Part 178**—Indirectf ood additives: Adjuvants, Production Aids & Sanitizers; Subpart D – Certain Adjuvants & production Aids; Sec **178.3620**.”

This is known as **FDA 21 CFR 178.3620 Mineral oil**, of which section (a) is for White oils meeting **21 CFR 172.878**, which is another FDA regulation establishing the tests for pharmaceutical white oils. The important tests are for the Readily Carbonisable Substances and Ultraviolet absorption (limit of poly nuclear compounds) to meet the requirements of the US Pharmacopoeia and of the Journal of the Association of Official Analytical Chemists (JAOAC). This latter requirement would normally expect to be less than 0.10 at wavelengths of between 260 - 350nm for medicinal white oils.

Section (b) of the 178.3620 regulation relates to “Technical White oils” with a less severe ultraviolet absorbance requirements than (a).

What Other FDA regulations are there?

There are a number of other classifications issued by the FDA that of interest to the oil industry, including those for “Lubricants with incidental food contact”, (178.3570) and “Surface lubricants used in the manufacture of metallic articles”, (178.3910).