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FDA to scrutinize unproven alternative remedies (Update)

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Federal officials plan to review the safety and evidence behind alternative remedies like Zicam and Cold-Eeze, products that are protected by federal law, but not accepted by mainstream medicine.

The Food and Drug Administration says that it will hold a two-day meeting next month on regulations for homeopathic medicines, which have long occupied a place on the fringes of U.S. health care. Similar to dietary supplements, homeopathic products are not required to prove they are safe or effective before being sold on the market. But unlike supplements, homeopathic medicines state that they are designed to treat specific medical conditions.

According to a federal notice published online Thursday, the FDA will ask attendees whether there is data to "better assess the risks and benefits" of homeopathic medicines. Regulators also have questions about the appropriateness of selling some homeopathic drugs without a prescription. Regulators said that many of the medical indications listed on homeopathic drugs "have never been considered for over-the-counter use under a formal regulatory process."

Homeopathic products have grown into a multibillion-dollar U.S. market since the FDA last reviewed its oversight of the products 25 years ago, the agency notes.

Zicam and hundreds of other homeopathic remedies are often sold alongside over-the-counter drugs like Tylenol and aspirin at pharmacies

across the U.S. But homeopathic medicine is based on a principle unverified by mainstream science: that substances that create certain symptoms in healthy people are effective in treating the disease that causes the same symptoms.

A key principle of traditional homeopathy holds that the more diluted a remedy is, the better it works. Today, many remedies marketed as homeopathic contain heavily diluted drug ingredients, vitamins or minerals. For instance, Zicam contains a heavily diluted dose of zinc as its "active ingredient."

In 1938, Congress passed a law granting homeopathic remedies the same legal status as regular pharmaceuticals. The law's principal author was Sen. Royal Copeland of New York, a trained homeopath. And that law has remained in force ever since.

Many scientists view homeopathic remedies as modern snake oil—ineffective but mostly harmless because the drugs in them are present in such tiny amounts. According to the National Institutes of Health, most research has concluded that "there is little evidence to support homeopathy as an effective treatment for any specific conditions."

In the early 1970s, Congress directed the FDA to review the safety and effectiveness of all drug ingredients used in over-the-counter medicines. But the agency delayed reviewing homeopathic products "due to the uniqueness of homeopathic medicine," according to the federal notice. "To date, FDA has not reviewed this class of products for safety and efficacy."

No votes or formal recommendations are planned for the FDA meeting, scheduled for April 20 and 21. The FDA plans to take comments and input from the public, including industry officials, health practitioners

and consumers.