Cholesterol-busting products provoke FDA

It spreads like a soft margarine, tastes like a soft margarine, and contains the same fats as the most heart-healthy of soft margarines. But is Benecol—McNeil Consumer Healthcare Product Co.'s new dietary product—actually a margarine?

The Food and Drug Administration says it is, and so it must meet stringent food-safety regulations. McNeil counters that it's a cholesterol-lowering dietary supplement, subject to less strict rules. Last week, this dispute ignited intense discussions between the parties. Who prevails will determine when Benecol, which has been gobbled up by Finns for the past 3 years, finally debuts in North America.

At the heart of Benecol's challenge is its unique ingredients: stanol esters derived from plant relatives of cholesterol (SN: 5/30/98, p. 348). The gut, mistaking the compounds for cholesterol, tries to absorb them, but the mimics are just different enough from cholesterol that only traces get through the intestinal wall. Meanwhile, as the gut tries to absorb the stanol esters, it largely ignores any real cholesterol present.

McNeil, which is based in Fort Washington, Pa., acquired global rights to produce Benecol outside Finland and reformulated the spread's recipe. It now contains more cholesterol-lowering monounsaturated fats than the original and less cholesterol-raising saturated fats. Neither recipe contains *trans* fats, which also can elevate cholesterol.

McNeil had planned to introduce the spread in Oregon supermarkets last week, followed by a national rollout of the product in January. If considered a dietary supplement, Benecol wouldn't need FDA approval as long as McNeil documented the product's safety and gave 30 days' notice of its intentions to market it.

McNeil supplied data not only on the safety of stanol esters but also on Benecol's efficacy. The strongest evidence comes from a 1995 study of Finnish men with moderately elevated cholesterol. After using about three pats a day of Benecol instead of margarine for 1 year, their blood concentrations of low-density-lipoprotein (LDL) cholesterol, the so-called bad cholesterol, fell by as much as 14 percent.

More recently, Tu T. Nguyen and his colleagues at the Mayo Clinic in Rochester, Minn., demonstrated that McNeil's recipe performs comparably. At the American Dietetic Association meeting in St. Louis last month, they showed that it lowers LDL concentrations by an average of 22 milligrams per deciliter of blood, or again 14 percent. Indeed, Nguyen observes, "we got the same response in 8 weeks that [the Finnish study] got at 1 year."

FDA probably wouldn't have challenged the stanol esters if they were packaged as a pill. But delivering them in a margarine substitute makes Benecol a food, FDA says, and federal law prohibits the sale of foods containing additives that the agency has not approved as safe. Not only is the safety standard for such additives higher than that for supplements, but FDA must pre-approve any additive before it is sold—as it did the fat substitute olestra 2 years ago (SN: 2/3/96, p. 69).

McNeil has argued that consumers are unlikely to shell out $16 a pound for Benecol merely to flavor their bread. Lowering cholesterol would have to be a primary concern. This distinction points out why Benecol is less a food substitute than a supplement delivered in the guise of a food, explains McNeil spokeswoman Amy Weiseman.

Last May, FDA mounted a slightly different challenge to Cholestin—capsules of rice fermented with a red yeast. Since April 1997, Pharmanex of Simi Valley, Calif., has marketed this product as an all-natural, cholesterol-lowering food supplement. Though FDA doesn't quibble with the capsules' efficacy, it argues that their active ingredient is the natural analog of a cholesterol-lowering prescription drug.

Charging that this makes Cholestin a drug, FDA ruled 6 months ago that the product should not be sold until it satisfies the agency's stringent drug-safety and efficacy rules. Pharmanex sued FDA over this decision. It argued that its red-yeast product should qualify as a supplement because it has been used as a spice and food coloring in China for millennia and is legally found in countless Chinese-grocery and restaurant offerings throughout the United States.

In June, a U.S. district court temporarily agreed with Pharmanex, so Cholestin remains on the market and is available in 35,000 U.S. stores. The court expects to issue a final ruling on Cholestin's supplement status in January. —*J. Raloff*

Tongue ties across continents draw fire

Reconstructed words from language families in central Siberia and North America show noteworthy similarities, according to a new study. The finding supports a controversial theory on the Asian origins of prehistoric migrants to the New World.

However, some language researchers familiar with the new analysis view it as a small collection of linguistic similarities that most likely occurred by chance.

Linguists have long held that both the Yeniseian languages in Siberia and the Na-Dene languages in North America have no known relatives among other languages in the world. But similarities between these two geographically separated language families suggest that they shared a common origin in central Asia, with one population of speakers trekking over a land bridge to North America several thousand years ago and another settling in Siberia, contends linguist Merritt Ruhlen of Stanford University.

He suspects that the findings will help to locate the source of one of three ancient migrations to the Americas proposed by Stanford linguist Joseph H. Greenberg in a much-contested theory (SN: 6/9/90, p. 360).

Ruhlen, whose report appears in the Nov. 10 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, compared the Yeniseian language family—which today consists only of Ket, a language spoken in central Siberia—to the Na-Dene family, which includes several languages spoken mainly in western Canada and Alaska. Using linguistic evidence on current and past tongues in these families, Ruhlen constructed root words, or protowords, that represent what he considers to be ancestral versions of Yeniseian and Na-Dene.

The two reconstructed languages share 36 protowords with similar meanings and sounds, the Stanford researcher contends. These include terms for body parts, such as elbow, foot, and head; plants and natural phenomena, such as birch bark, river, and falling snow; animals, including deer and owl; tools and utensils, such as boat and rope; and some other basic words, such as dry, hunger, and night.

Ruhlen considers especially compelling his finding that the Ket word for birch bark is almost identical to a root word meaning either birch bark or birch tree in Athabaskan, a subfamily of Na-Dene.

"I think this [study] is pretty conclusive evidence for a connection between these language families," Ruhlen says.

Ruhlen belongs to a minority of linguists that believes that credible methods exist to find links between far-flung languages and to reconstruct ancient roots of modern tongues. Other linguists view these efforts with extreme skepticism.

"Ruhlen's findings look like chance resemblances to me," comments Athabaskan specialist Michael Krauss of the University of Alaska, Fairbanks.

Ruhlen would need to document many more word similarities, using more rigorous consonant-by-consonant comparisons, to demonstrate a genuine link between Yeniseian and Na-Dene, remarks Johanna Nichols of the University of California, Berkeley. She also doubts that a valid protoversion of Yeniseian can be devised. —*B. Bower*