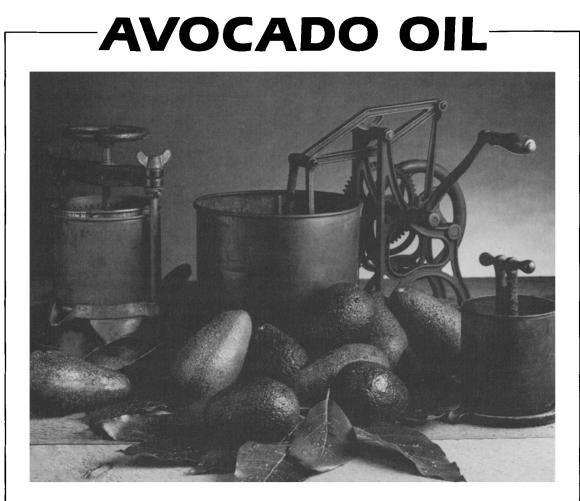
# Features



# -FROM FOOD USE TO SKIN CARE-

The following article about the California avocado and its oil was prepared by Horton E. Swisher, a consultant, of Covina, California. Requests for further technical or market data should be sent to AVOCO, PO Box 1170, Covina, CA 91722.

The avocado (Persea Americana Mill) is a fruit of unusually high oil content and a relatively high concentration of chlorophyll under the skin, giving the oil an attractive emerald green color. In Europe and Asia, avocado oil has a certain mystique which long has been recognized. Currently, avocado oil is beginning to receive considerable attention in the U.S.

Just as the olive and its oil have a special place as a gift from the "Old World," the ubiquitous avocado and its oil are now assuming the recognition due a unique fruit from the ancient Mayan and Aztec Indian civilizations of the "New World." Although the historical aspects of the avocado are lost in the mists of time, these Indians long ago had discovered its beauty secrets and it was known as an aphrodisiac or "love food."

In the early 1500s, the Franciscan priest Toribio de Motolinia recorded his observations in his *History of the Indians of New Spain*: "Among the fruits found in the mountains around Puebla (Mexico) is one they call 'ahuacatl,' which hangs on the tree and looks like a large pear. The fruit is so wholesome that it is served to the sick. Water prepared from the broad, green leaf is good as a remedy for the legs and even better for the face."

Of the three recognized varieties of avocado, based upon their ecological origin, the two most important varieties in the California avocado industry currently are the Fuerte, a Guatemalan/Mexican hybrid, and the Hass, which originated from a Guatemalan seedling. The principal variety is the Hass, developed by Charles Hass in his backyard in Gardena, California.

Although ally classified the avocado fore, avoca should be maturity, the oil content of avo cados of the Mexican variety is much higher than that of the other two and especially of the West Indian variety. Florida avocados, which are of the West Indian type, and their hybrids have a decidedly lower oil content at maturity than is found in the leading California varieties. The oil content of California avocados usually ranges from 15 to 30%, whereas Florida varieties are in the range of 5-18%.

This variation in oil content is mainly attributed to the origin of the fruit. As would be expected, the fatty acid composition of the lipids of the avocado fruit and the oil varies with different cultivars, stages of ripening, anatomical region of the fruit and geographic growing location. The major fatty acid is always oleic, followed by linoleic, palmitic and palmitoleic. Trace amounts of linolenic and stearic also are present.

# **Physiochemical properties**

The fatty acid profile for fully refined California avocado oil is given in Table 1. The oleic acid content of avocado oil (range of 69–74%) is high and this omega-9 monounsaturated fatty acid is quite stable. Avocado oil and olive oil overlap in their content of oleic acid, a monounsaturated fatty acid, now considered highly desirable to include in the "prudent" diet.

Further data relating specifically to California avocado oil are shown in Table 2.

# Color of oil

The color of fats and oil is an important characteristic; consumers indicate a preference for shades according to their expectancy for that kind of oil. In the case of avocado oil, the green chlorophyll layer under the skin imparts considerable green color to the crude oil. After refining, the oil is more of a yellowgreen.

# Smoke point

When avocado oil is used as a heat

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ied as a vegetable oil, o is a fruit and, there-	TABLE 1
ado oil more properly called a fruit oil. At	Fatty Acid Profile of Refined Avocado Oil
the oil content of avo-	Fatty acid

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a dooy dord		rercentage
Palmitic	16:0	9 -13
Palmitoleic	16:1	2.8- 4
Stearic	18:0	0.4- 1
Oleic	18:1	69 -74
Linoleic	18:2	10 -14
Linolenic	18:3	1 - 2
Arachidic (Eicosanoic)	20:0	Trace amounts

Source: AVOCO files.

#### TABLE 2

Specifications for California Avocado Oil

	Crude oil	Fully refined oil
Color	light to dark green	clear yellow
Free fatty acids (FFA)	1-3%	0.03-0.5%
Iodine value (Wijs)	80-90	85-90
Specific gravity at 25 C	0.910-0.920	0.910-0.920
Refractive index at 25 C	1.460-1.470	
Saponification value	-	177-198
Source: AVOCO files.		

exchange media, particularly for stir-fry cooking, the smoke point is of considerable importance. The smoke point of refined avocado is around 490°F. Because the smoke point is related to the free fatty acid (FFA) content of the oil, it is desirable to keep the free fatty acids quite low.

### Oil processing and refining

Although several methods for the recovery of avocado oil from the pulp have been practiced, the preferred method for obtaining pure natural oil without solvent impurities is by centrifugation. Obtained in this manner from whole ripe avocados, the crude oil is dark green and has a chlorophyll content of 40 parts per million (ppm) or more. Because the green oil has a natural appearance suggesting its avocado origin, this oil may be the choice for some uses such as for cosmetic products. However, the refined clear oil is generally preferred for food uses.

The crude avocado oil may be

partly or fully refined as required for its end use. As crude oil, it contains variable amounts of particulate matter, waxes and phosphatides which are normally separated in the refining process.

Steps involved in total processing of crude avocado oil to the more highly refined oil include alkali refining, bleaching, deodorization and winterization before drumming. Analyses of the refined oil include iodine and peroxide values, color, appearance and free fatty acids (FFA).

### Food uses

The trend today is toward a return to anything natural, whether it is for food or skin care. Pure avocado oil is a naturally good product, light and delicate in character, and contains no cholesterol. Its flavor is very mild, with a slight suggestion of nuttiness, and blends well with nearly any food.

Currently, there is much interest in the monounsaturated fatty acids. The high level of oleic acid,

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the stable, omega-9 monounsaturated fatty acid such as that found in avocado and olive oil, is suggested to be of considerable health value. The influence of diet on serum cholesterol has been amply demonstrated in a number of studies. A typical fatty acid profile of avocado oil shows it to be monounsaturated to a high degree, upward of 75%, based on a yearly average. These monounsaturated In the cosmetic and toiletry field, the search is now toward more scientific or quasiscientific uses that really do something good for the skin. Avocado oil has been found to have special properties of interest for cosmetic formulations. Among these are its emollient nature, its rapid absorption into the skin and its ability to act as a natural sunscreen. A research paper by Vollete and Sobrin reported on

In the cosmetic and toiletry field, the search is now toward more scientific or quasiscientific uses that really do something good for the skin.

oils have now been found to play a more important role in affecting serum cholesterol and lipoproteins than previously thought.

Avocado oil has exceptional properties for food preparation. Among these are its use in salads, for marinades, in sauté and stirfry dishes and in sauces.

#### Skin care uses

Although the Europeans and Japanese have been aware of the special value of avocado oil in skin care products for some time, this recognition has come much more slowly in the U.S. Because of controversy in the European market about certain chemicals used in cosmetics, some companies are looking more seriously at the "natural" concept. In The Netherlands, natural cosmetics at health products shops are booming. This is also true in the U.K. for attractively pared-down packaged products, which have proven to be a retailing success.

the skin-penetrating properties of a number of oils using a pharmacodynamic method.

Although skin generally is not highly penetrable to oils, noticeable differences were observed in the oil's ability to transport active substances. Of the oils tested, avocado oil had the highest rate of skin penetration in the group which included corn, soybean, almond and olive oils. Potentially, this could be of aid in carrying useful compounds through the outer epidermis of the skin and into the dermis for increased effectiveness.

Sunburn preventatives contain substances that serve as chemical or physical "parasols." Such a sunscreen should be nontoxic and nonirritating, preferably colorless, have some solubility in aqueous alcohol or oil solvents and be effective for a stated period of time. Such chemical sunscreens as PABA (para amino benzoic acid) are highly effective, as compared with natural oils, but are not the choice for those who prefer such products of nature as represented by avocado oil. The following (adapted from the *Encyclopedia of Chemical Technology, Vol. 7*) lists several natural oils in the order of their effectiveness as sunscreens (the first ranking as the most effective):

- Mink oil
- Avocado oil
- Sweet almond oil
- Sesame oil
- Persic oil
- Safflower oil
- Peanut oil
- Jojoba oil
- Coconut oil
- Olive oil

Toxicological test data from human and animal studies using avocado oil, as well as cosmetic formulations containing avocado oil [as reported in the Journal of Env. Path. and Toxicology, Vol. 4(4), pp. 93-103, 1980] gave a final safety assessment for avocado oil. This cosmetic ingredient review supported the conclusion that avocado oil, as currently used in cosmetic formulations, is considered safe. In the U.S., after ten years of public use of cosmetics containing avocado oil, there is no evidence of incompatibility with the skin.

Product formulation data from the files of the U.S. Food and Drug Administration (1976) show a total of 240 products containing avocado oil in concentrations ranging from 0.1 to 50%. The uses for avocado oil include cleansing creams, moisturizers, skin care, hair conditioners, lipstick, suntan lotions, bath oils and makeup bases.

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# Fat substitutes create new issues

The following article, prepared by JAOCS newswriter Anna Gillis, explores issues, particularly regulatory questions, raised in the food industry concerning specially created fat substitutes. Such substances have yet to gain affirmation or approval from the U.S. Food and Drug Administration.

Nutrition experts and marketing specialists expect calorie-conscious consumers to accept fat substitutes with the same alacrity and enthusiasm they have displayed toward sugar substitutes. Financial analysts forecast fat substitutes may match or even surpass the success of sugar substitutes, given the number of products that contain fat. Fat substitutes could find a major niche in spreads, snacks, salad dressings, cooking oils and other foods, so much so that product sales eventually could total billions of dollars a year.

Preliminary results from a study on fat substitutes conducted by Experience Inc., a Minneapolis-based consulting firm, show that food industry scientists foresee a high level of usage for the substances and consumers believe there will be acceptance of fat substitutes as food ingredients. "At this early stage of our work, it appears that several hundred million pounds of vegetable oils and fats could potentially be replaced if regulatory and marketing strategies allow for full exploitation of the options," Ray Dull, a consultant with Experience Inc., said.

"The American public is ready for fat substitutes,"according to Joseph Hotchkiss, a professor of food science at Cornell University. Hotchkiss, who formerly worked for the U.S. Food and Drug Administration (FDA), compared the potential of fat substitutes to aspartame and noted that, if fat substitutes become commonly used in food products, there is concern that "the amount consumed may be astronomical."

The two fat substitutes currently touted as having the greatest marketing potential are olestra, developed by The Procter & Gamble Co. (P&G), and Simplesse, a NutraSweet Co. product. Olestra, a caloriefree fat substitute, is a mixture of octa-, hepta- and hexaesters formed by the reaction of sucrose with long-chain fatty acids. Although it has the physical properties of dietary fats, it cannot be absorbed, according to the company. Simplesse, a dairy-based fat substitute made from egg and milk proteins, is produced through a heating and blending process called microparticulation. According to NutraSweet, Simplesse has 1 1/3 calories per gram. Unlike olestra, Simplesse cannot be used in baking and frying because the protein hardens when heated.

Neither compound has received government approval or affirmation. FDA currently is reviewing P&G's petition for food additive status for olestra; NutraSweet has yet to seek FDA review. In its petition, P&G has asked FDA to approve the use of olestra as an ingredient in shortenings, oils and certain salted snack applications. If approved, olestra could comprise up to 35% of fats in home cooking oils and shortenings and 75% of the fats in commercial cooking oils and snack foods. NutraSweet has said it will submit a petition later this year to seek affirmation as Generally Recognized as Safe (GRAS) for Simplesse.

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Other companies – CPC International Inc., Frito-Lay and Unilever N.V. – hold fat substitute patents but have not sought FDA approval. Arco Chemical has sought patent protection in Europe. Pfizer Inc. received a patent for the bulking agent polydextrose in 1970 and gained FDA approval in 1981.

# The approval process

FDA review can be a complex and lengthy process. P&G filed its FDA petition, along with thousands of pages of data, in May 1987. The agency has not yet divulged whether it will sanction the use of olestra nor indicated how long its review will take.

"FDA's average time for reviewing petitions is 18 months from time of filing to final regulation," according to Gerad McCowin, who directs FDA's Division of Food and Color Additives (the office responsible for managing the evaluation of P&G's petition). McCowin said the agency will evaluate olestra in the same way it evaluates any other food additive: study the substance and then determine how much is likely to enter the daily diet. Also, he said, FDA will want to know how the substance may affect the overall diet and what imbalances the product might introduce.

In the nutrition community, there is some concern olestra may limit a person's ability to absorb fat-soluble vitamins. If this is the case, "it underscores the need to increase vitamin levels in people who may consume large amounts of fat substitutes," Hotchkiss said. FDA must consider how consumption might influence absorbtion of fat-soluble vitamins and what effect long-term consumption of large nonabsorbable molecules might have on the gastrointestinal tract, he added.

According to P&G spokesman Don Tassone, "P&G has found that olestra may cause problems with the absorbtion of vitamin E in some people." Consequently, he said, "P&G has recommended to FDA that the product be supplemented with modest amounts of vitamin E."

Sanford Miller, formerly director of FDA's Center for Food Safety and Applied Nutrition and now dean of the Graduate School of Biomedical Sciences at the University of Texas Health Science Center at San Antonio, pointed out that FDA is likely to examine these substances carefully because fat substitutes might be used by all sectors of the population. "The major difference between olestra and other food additives will be the amounts consumed. Other additives may make up 1-2% of a food. Fat substitutes may represent 30-40%," Miller said.

Given the potential prevalence of olestra and other fat substitutes, FDA's decision will be a "key first from a regulatory standpoint," according to Ted Labuza, professor of food science at the University of Minnesota and president of the Institute of Food Technologists. Labuza speculated that if FDA gives approval to fat substitutes, the regulations for olestra are likely to be more stringent than than those for Simplesse. "Something like Simplesse, which is a cooked protein, I would expect to be approved under GRAS," he said.

If NutraSweet wants FDA to affirm Simplesse as GRAS, it will either have to show a history of common use in food before 1958 or have a panel of experts determine through scientific procedures that the substance is safe, according to McCowin. For the latter route, NutraSweet would have to supply the same type of information required for food additive status, and also show that supporting studies are in the published literature. The last requirement is "built out of a concern that if the information is not in the literature, then there may not be general recognition by the scientific community as to the safety of the substance," McCowin added.

"Where FDA is concerned, all food is guilty until proven innocent," Hotchkiss said. NutraSweet has not indicated which route it will take in its GRAS application but, Hotchkiss pointed out, the "burden of proof" is often lighter when showing a history of common use. "NutraSweet will have to convince FDA that Simplesse is innocuous. Most people would agree that proteins are safe."

According to Hotchkiss, rearrangement of foods raises interesting scientific and legal questions: Will the rearrangement of a traditionally GRAS food make it unsafe, and can a rearranged food be considered as safe as the food from which it is derived? A NutraSweet spokeswoman, however, said Simplesse is not rearranged, but rather cooked—or aggregated—protein, using the protein's ability to gel to obtain the shape desired.

Consultants to the food industry say any decisions FDA makes in the fat substitutes area will be important precedents for the food industry. "The issue of Simplesse is important in the long term where food is concerned. The ability of a company to take parts of a naturally occurring approved substance and change them for use in foods will be a regulatory issue," Dull said. He pointed out that adding or deleting traits from already approved foods could cause "regulatory perplexity."

Sandra Panem of Salomon Brothers called olestra "a demonstration case." "As the power of biotechnology increases, FDA will face a whole new class of foods," she said. This class of foods will force FDA to look for new procedures and develop different evaluation guidelines, she said.

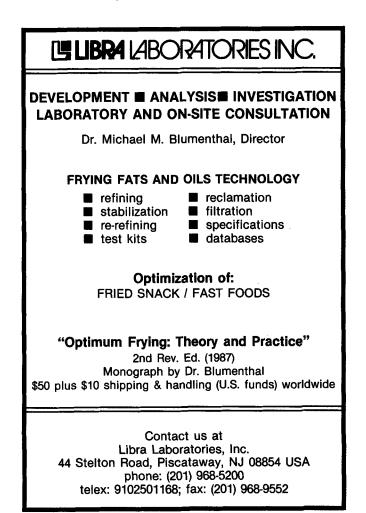
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#### A new class

FDA representatives and former officials don't agree that fat substitutes belong in a distinctive class for evaluation purposes. Although fat substitutes themselves are not food, they are no different than any other component in the diet in that they fall under the food section of the Food, Drug and Cosmetics Act, according to Miller, who pointed out that the act does not strictly define food. Section 201f of the act says food includes "articles used for food or drink for man or other animals, chewing gum and articles used for components of any such article."

FDA does not classify fat substitutes as a new class of foods per se, according to F. Edward Scarbrough, the deputy director of the Office of Nutrition and Food Science. However, Scarbrough said, fat substitutes are different from other food additives in that they could represent up to one-third of the calories consumed. The possibility that large amounts might be eaten means it will be impossible to carry out test dosages at the exaggerated level usually used previously, Scarbrough said.

Traditionally, FDA makes its safety recommenda-



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tions for noncarcinogenic food additives based on the "no effect level." Test animals are dosed with varying amounts of a compound in order to find the highest level in terms of milligrams per kilogram of body weight per day at which the substance does not adversely affect the animals. This level is used to establish an acceptable daily intake by dividing the "no effect level" by a margin of safety, usually 100 or 1,000, depending on the study.

That level is considered the benchmark of safety. The actual levels approved depend on the amounts needed to get desired technical effects, Miller explained. The approved level cannot exceed the safe level and, in many cases, may be much lower.

The testing of fat substitutes creates scientific problems not normally found with more traditional food additives, according to Miller. "How do you test major food components? Usually, we'd give high dosages, 100 times more than would normally be consumed, but how do you feed a fat at 100-fold levels?"

The way around the problem is to conduct human studies instead of animal trials, and a company can only do that by applying for new drug status with FDA. This was the approach used by P&G, according to Miller. Usually, petitioners don't have to go this route because food additives don't make up a huge portion of the diet, but as more of these products enter the regulatory process, FDA may have to address them in a different way, Miller said. One way would be to establish experimental food additive rules that would regulate clinical trials. "The act provides for these kinds of regulations; they just have not been needed before," he said.

# Labeling

Regulations approving the use of fat substitutes would contain labeling requirements to ensure the safe use of the substances and prevent consumers from being

# Sessions feature fat substitutes

AOCS will hold three technical sessions on fat substitutes at its 1989 annual meeting, scheduled for May 3-7, 1989, in Cincinnati, Ohio. Analytical methodology, health benefits and incorporation into food products are among the topics to be covered. Representatives from The Procter & Gamble Co., Experience Inc. and James River Corp. are among the participants who will present papers. Representatives from academia and government also have been asked to participate.

Others interested in presenting a paper or in suggesting a topic should contact Technical Program Chairman Bryan Madison by Dec. 15, 1988. He can be reached at The Procter & Gamble Co., 6071 Center Hill Rd., Cincinnati, OH 45224, telephone 513-634-7437. mislead, McCowin said. "In considering labeling, the agency looks at whether the consumer would be adequately informed about the product in terms of safety. For example, aspartame is required to carry a declaration of the presence of phenylalanine." (An accumulation of phenylalanine and its metabolites can cause brain damage in people deficient in the enzyme phenylalanine 4-monooxygenase.)

No specific labeling issues have yet been addressed by the Office of Nutrition and Food Science, Scarbrough said. Nutrition experts said fat substitutes would likely meet requirements for reduced-calorie and lowcalorie standards. However, fat substitutes may raise questions in the imitation food area, according to Labuza.

FDA requires a food to be labeled as imitation if it resembles another food and can be substituted for it, yet is nutritionally inferior to the food it imitates. According to Scarbrough, certain components of foods are exempt from consideration when determining nutritional inferiority. Imitation labeling revolves around vitamin and protein content more than fat content, he explained, adding that a reduction in calories would not cause a food to be an imitation as long as there is no lowering of nutrient value. Because fat substitutes would appear in reduced-calorie foods, they would not likely require imitation labeling, McCowin said. "They would just be listed as part of the ingredients."

However, if a company chose to use fat substitutes in dairy-like products, present food standards regulations for dairy products would prevent a company from calling the product a dairy product, Scarbrough said. The label would have to clearly distinguish the product (containing a fat substitute) from products covered by the standards with either the word imitation or a completely new name, he explained.

Labuza questioned whether fat substitutes should be exempt from labeling requirements for imitation products. "FDA deems imitations nutritionally inferior if they don't meet certain vitamin and protein requirements," Labuza said, adding FDA's eight nutritional standards may not be enough to determine nutritional adequacy as more substitute products are developed. If fat is cut from the diet, "there could be losses at the micronutrient level," he added. In the development of foods, "maybe we need other standards to determine the benchmark of nutritional acceptability."

Miller, likewise, is concerned with the nutritional parameters of created foods. "Theoretically, artificial foods may be produced that have no nutritive value, but have all the organoleptic qualities of regular foods," he said. "It would be the creation of the ultimate food for anorexics. This could be a serious situation. The potential for creating these products makes one ask whether every food construct should provide a minimal amount of nutrients."

A NutraSweet spokeswoman, however, is quick to point out that unlike olestra, Simplesse should not be considered nonnutritive as it would be a protein substituted for a fat.

Although fat substitutes raise a number of interesting and difficult questions, Labuza said new technologies provide exciting alternatives to the food inFeatures

dustry. "Food must still be safe and should fit into the proper dietary context. It will be the job of food scientists and nutritionists to educate the public in terms of how much of these products to eat so that there is a balance in the diet."

# The search for fat substitutes

A number of companies interested in the ever-expanding low-calorie food market have carried out extensive research to find the perfect fat substitute. The goal is a compound with the functional and organoleptic characteristics of fat but with as few calories as possible. A few firms have successfully developed fat substitutes and have sought patent protection for their inventions.

Before companies can begin marketing fat substitutes, FDA must determine that the products are safe. The following table lists the major companies working in the area and the progress they've made in fat substitute development.

# **ARCO Chemical Co.**

ARCO Chemical Co. in Newtown Square, Pennsylvania, has developed a noncaloric fat substitute from esterified propoxylated glycerol (EPG) which in turn is manufactured from propylene oxide. The company has reported that preliminary studies indicate that EPG is not only noncaloric but also safe and effective as an oil and fat replacement. Its potential applications include conventional oils, salad dressings, baked goods, spreads and ice cream. ARCO applied for patent protection in the European Economic Community (EEC) earlier this year.

# **CPC** International Inc.

CPC International Inc., Englewood Cliffs, New Jersey, has looked at trialkoxytricarballylate (TATCA), trialkoxycitrate (TAC), trialkoxyglyceryl ether (TGE), sucrose polyester and refined jojoba oil as possible low-calorie replacements for conventional edible fats and oils. In April 1985, the company received a patent for a low-calorie edible oil substitute made from thermally stable polycarboxylic acids esterified with saturated or unsaturated alcohols. The company has not applied for U.S. Food and Drug Administration (FDA) approval.

# Ethyl Corp.

Ethyl Corp., Richmond, Virginia, received a patent in 1982 related to low-calorie fats for food.

# Frito-Lay

Frito-Lay, Dallas, Texas, has received two patents for its work on synthetic oils. The company is continuing its research on synthetic oils and plans to submit one or both of its patented products to FDA for review. A company representative said it would be at least five years before market testing could begin.

#### Mitsubishi-Kaisei Food Corp.

Mitsubishi-Kaisei Food Corp., Tokyo, Japan, introduced sucrose polyesters to Japan in 1984 where they have been used as lubricating agents in pharmaceutical tablets, anticaking agents in powdered products and as oil-in-water emulsifiers for processed fat products. According to Mitsubishi, they improve heat stability in coffee whiteners, prevent foaming in tofu production and can be used in chocolate enrobing to prevent blooming. The sucrose polyesters are used for their functionality rather than in low-calorie food applications in Japan. The company has not decided whether it will introduce its sucrose polyesters into the U.S.

#### NutraSweet Co.

The NutraSweet Co., Deerfield, Illinois, unveiled Simplesse, its low-calorie fat substitute in January 1988. At that time, NutraSweet claimed that Simplesse would not have to go through FDA because it was made from protein and only its physical form was changed during processing. FDA has since said the product would fall under its jurisdiction, and Nutra-Sweet would have to seek affirmation for the substance. The company said it will seek affirmation as Generally Recognized as Safe (GRAS) for Simplesse by the end of this year. Because the protein hardens when heated, Simplesse cannot be used in baking and frying applications.

#### **Pfizer Inc.**

Pfizer Inc., based in New York, holds a patent on polydextrose which functions as a bulking agent, texturizing agent and humectant. The substance, made from dextrose, sorbitol and citric acid, provides one calorie per gram. It received FDA approval in June 1981, and since then has been used as a partial replacement for sucrose and fats to produce low-calorie and reduced-calorie foods.

# The Procter & Gamble Co.

Olestra, the fat substitute created by The Procter & Gamble Co. (P&G) based in Cincinnati, Ohio, is undergoing FDA review. In May 1987, P&G submitted a petition asking that FDA permit olestra's use as a food additive in shortenings and oils for home use and in commercial cooking oils. The substance is produced from sucrose polyesters and is nonabsorbable, so therefore is calorie-free. Olestra can be used in cooked and uncooked foods and is covered by numerous patents.

#### Unilever N.V.

Unilever N.V., Rotterdam, The Netherlands, holds one patent for sucrose polyester (SPE) and has filed a number of other applications in the U.S. and Europe for the production and use of SPE. Although Unilever is interested in manufacturing sucrose polyesters for various food products, it believes more research is needed for all sucrose polyesters. According to a spokesman for Unilever United States Inc., the company will not seek FDA approval for SPE until it "is fully confident of the long-term effects of SPE."