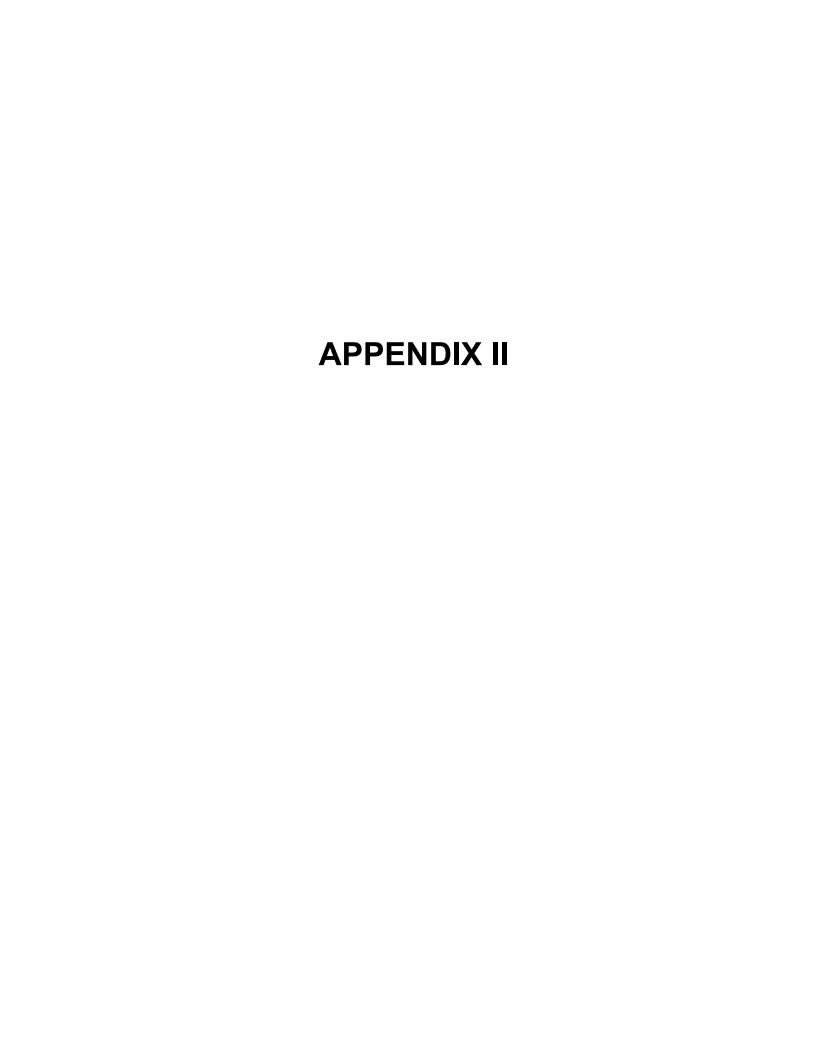


Center for Food Safety and Applied Nutrition Ten Year Budget Summary for OFL, OSN and ONPLDS Center/Field Activities FY 1993-FY 2002*

Appendix I

Fiscal Year	Total Center	Total Center	Total Field	Total Field Dollars
	FTEs	Dollars	FTEs	
1993	98	\$6,023,000.00	66	\$4,200,000.00
1994	105	\$7,077,000.00	64	\$4,200,000.00
1995	98	\$6,915,700.00	97	\$6,600,000.00
1996	97	\$6,719,500.00	89	\$6,400,000.00
1997	94	\$6,907,900.00	65	\$4,800,000.00
1998	83	\$6,671,289.00	58	\$4,500,000.00
1999	83	\$7,449,400.00	50	\$4,100,000.00
2000	83	\$7,560,500.00	52	\$4,300,000.00
2001	73	\$6,864,000.00	51	\$4,800,000.00
Est. 2002	70	\$6,647,543.00	59	\$5,900,000.00

^{*}This information was supplied to CSPI by FDA on May 8, 2002 in response to CSPI's Mar. 5, 2002 Freedom of Information Act request. All figures are expressed in current dollars.



Examples of Pending ONPLDS Petitions Submitted from 1991-2002 Appendix II

Docket #	Petition Date	Petitioner	Summary
91P-0050	Feb. 11, 1991	Michael Foods, Inc.	Requests that FDA amend the Standard of Identity for liquid eggs to permit ultra pasteurized liquid whole eggs.
91P-0051	Feb. 13, 1991	Producers and distributors of cooking wine represented by Olsson, Frank & Weeda.	Requests that FDA propose and adopt a common or usual name regulation to codify the name "cooking wine."
91P-0297	Mar. 29, 1991	Nutrients Incorporated	Requests that use of the term "mineral salts" be permitted.
91P-0234	Jun. 17, 1991	Lois M. Meyer (FDA Employee)	Requests that FDA amend regulations for food labeling print size and color contrast to improve readability.
93P-0070	Feb. 10, 1993	Infant Formula Council	Requests that FDA establish an exemption from print size requirements for all infant formula.
93P-0227	Jun. 25, 1993	Center for Science in the Public Interest	Requests that FDA prohibit Keebler Co. and Nabisco Brands from using the term "whole wheat" in the common or usual name or brand name, and to identify products that contain white flour.
93P-0296	Aug. 4, 1993	National Soft Drink Association	Requests that FDA amend the regulation governing the placement of soft drink identity statements when the product is identified by a well-known trademark.
93P-0486	Dec. 15, 1993	Wine Institute	Requests that FDA amend its regulations to require the "not a significant source" disclosure statement to appear only when nutrients are added to food or voluntarily declared in the nutrition label or when nutrition claims regarding increased levels of nutrients are made on the label or in labeling.
94P-0029	Jan. 26, 1994	Calorie Control Council	Requests that FDA amend its regulations to require that "not a significant source" disclosure statement only when nutrients are added to food or voluntarily declared on the nutrition label or when nutrition claims regarding increased levels of nutrients are made on the label.

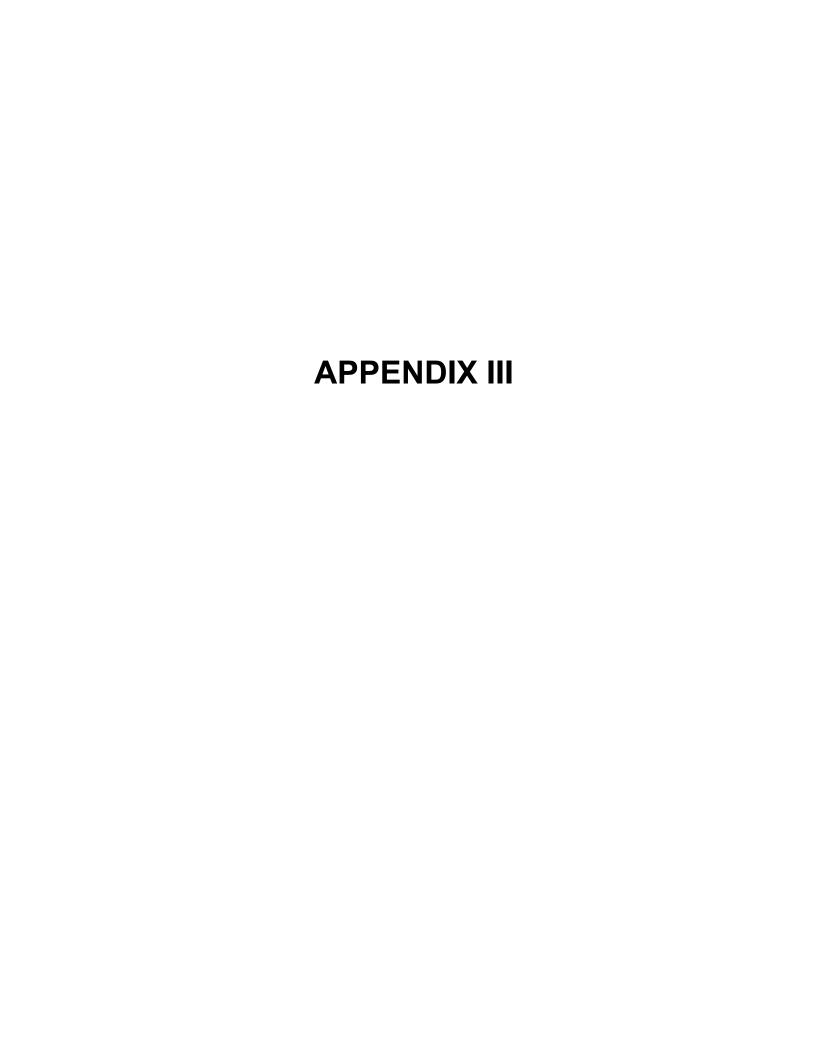
94P-0079	Feb. 4, 1994	National Soft Drink Association	Requests that FDA amend its regulations by deleting the words "or if any nutrition claims are made on the label or in labeling" as added by FDA's "technical amendments" to the final nutrition labeling rules and to make clear that the use of the simplified format is not limited by FDA rules.
94P-0187	May 20, 1994	Food Marketing Institute and National Grocers Association	Requests that FDA amend its ingredient labeling requirements applicable to foods prepared and packaged at retail stores.
94P-0293	Aug. 2, 1994	The Sugar Association, Inc.	Requests that FDA issue regulations to provide consistency in the use of the term "sugar" and "sugars" on food labels and labeling.
94P-0413	Nov. 14, 1994	National Pasta Association and the Millers' National Federation.	Requests that FDA amend the standards of identity for enriched macaroni and noodle products by replacing the range values for added nutrients with single values.
95P-0099	Apr. 4, 1995	Calorie Control Council	Requests that FDA amend the food labeling requirements to permit the use of the term polyols in lieu of sugar alcohols in the nutrition panel on the food label.
95P-0112	Apr. 25, 1995	Cancer Prevention Coalition	Requests that FDA require that hot dogs containing nitrites be labeled with a cancer risk warning, such as: "hot dogs containing nitrites have been shown to pose risks of childhood cancer."
95P-0241	Jul. 27, 1995	American Bakers Association	Requests that FDA amend two similar provisions in two regulations to govern the implied nutrient content claim "healthy" and the regulation governing general requirements for health claims.
95P-0246	Aug. 2, 1995	Center for Science in the Public Interest	Requests that FDA propose rulemaking and regulatory action to prohibit misleading food labeling, including claims that misleadingly imply that fruits, vegetables and whole grains are present in food in amounts greater than are actually the case.
95P-0392	Oct. 31, 1995	John Marion Ellis, M.D.	Requests that FDA issue an order to require fortification of foods with vitamin B6.
96P-0111	Apr. 4, 1996	American Cocoa Research Institute	Requests that FDA amend the nutrition labeling regulations to communicate the fact that stearic acid does not affect blood cholesterol.

96P-1043	Apr. 29, 1996	Calorie Control Council	Requests that FDA amend the food labeling regulations to permit the removal or reduction of an ingredient of standardized foods.
96P-0230	Jun. 26, 1996	Purac America, Inc.	Requests that FDA amend the regulations for designating food ingredients for black olives.
96P-0464	Nov. 27, 1996	Center for Science in the Public Interest	Requests that FDA prevent the unapproved use of the term "energy" on the labels of food packages.
97P-0043	Feb. 3, 1997	American Bakers Association	Requests that FDA amend the food definitions and standards of identity for bakery products and repeal the food definition and standard of identity for frozen cherry pie.
97P-0056	Feb. 10, 1997	Calorie Control Council	Requests that FDA permits a caloric value of not more than 2 calories per gram for soluble fiber in food labeling.
97P-0078	Feb. 28, 1997	Soyfoods Association of America	Requests that FDA issue a regulation recognizing "soymilk" as the established common or usual name to be used in labels and labeling.
97P-0130	Mar. 26, 1997	Center for Science in the Public Interest	Requests that FDA issue regulations to require percentage ingredient labeling for characterizing ingredients in foods.
97P-0142	Mar. 31, 1997	International Jelly & Preserve Association	Requests that FDA repeal the standards of identity for artificially sweetened jelly and preserves.
97P-0187	May 17, 1997	Nabisco, Inc.	Requests that FDA amend definition of "total fat" and "saturated fat" to clarify that acetic, propionic and butyric acids may be excluded when calculating the amount of fat in a food product.
97P-0329	Jul. 31, 1997	Center for Science in the Public Interest	Requests that FDA require quantitative disclosure of caffeine content.
97P-0498	Jul. 31, 1997	The University of Vermont	Requests that FDA require quantitative labeling of caffeine on food and beverage containers.
97P-0360	Aug. 16, 1997	Lt. Colonel Lighter	Requests that FDA require all packaged food to use an "open dating" system.
98P-0005	Dec. 15, 1997	International Specialty Products	Requests that FDA exempt drugs and food supplements containing carbonyl iron from special packaging and labeling requirements.
98P-0047	Jan. 13, 1998	The Association for Dressings & Sauces	Requests that FDA repeal the standard of identity for French dressing and revise the standards of identity for mayonnaise and salad dressing.

98P-0360	May 21, 1998	National Food Processors Association	Requests that FDA remove the labeling requirements for irradiated food.
98P-0418	Jun. 10, 1998	Center for Science in the Public Interest	Requests that FDA rescind the exemption from nutrition labeling and nutrient content claim requirements for the fat substitute olestra, and make changes to its nutrition labeling rules applicable to certain fats.
98P-0696	Aug. 10, 1998	Mr. Kenneth B. Lerman	Requests that FDA disclose all ingredients on food labels and labeling. If any of the ingredients are dead animals, the label should then indicate "Non-Vegetarian" at the end of the ingredient list.
98P-0724	Aug. 24, 1998	Center for Science in the Public Interest	Requests that FDA take a number of actions relating to the safety and labeling of cochineal extract and carmine color additives.
99P-0301	Feb. 22, 1999	The Procter & Gamble Co., Bestfoods and Hunt-Wesson, Inc.	Requests that FDA amend peanut spread regulations to remove the requirements for added vitamins, minerals and protein.
99P-0795	Mar. 30, 1999	Natural Resources Defense Council	Requests that FDA amend its regulations and policies on bottled water.
99P-2630	Aug. 3, 1999	Center for Science in the Public Interest	Requests that FDA establish a Daily Reference Value for "added sugars" in foods and require that the Nutrition Facts panel include the amount of added sugars and the percent Daily Value per serving.
99P-4208	Sep. 27, 1999	Center for Science in the Public Interest	Requests that FDA revise the labeling requirements for foods that contain sorbitol.
99P-5106	Nov. 17, 1999	Vegetarian Legal Action Network	Requests that FDA amend its regulations to require manufacturers to disclose the sources of natural flavors.
99P-5198	Dec. 2, 1999	American Dairy Products Institute	Requests that FDA amend the definition of milk to include fluid ultrafiltered milk.
00P-0425	Feb. 3, 2000	Mead-Johnson	Requests that FDA revise labeling and placement requirements for low-iron formulas.
00P-1211	Mar. 22, 2000	The Center for Food Safety	Requests that FDA implement regulations to prevent the commercial sale of all genetically engineered foods until the Agency takes certain steps outlined in the petition.

00P-1322	May 30, 2000	9 Attorneys General	Requests that FDA amend its rules and regulations regarding the labeling and manufacture of foods containing allergenic substances.
00P-1491	Aug. 30, 2000	Kraft Foods	Requests that FDA initiate rulemaking to amend the standard of identity for parmesan cheese.
00P-1572	Oct. 18, 2000	State of Alaska	Requests that FDA adopt a standard of identity for bottled water based on the source for glacier water and glacier-fed water.
00P-1680	Dec. 21, 2000	Protein Technologies International	Requests that FDA amend the definition and standard of identity for Parmesan cheese.
01P-0190	Apr. 23, 2001	Judy Zapka and the Center for Food Safety	Requests that FDA amend its labeling regulations to indicate that bottled diet Coca Cola and fountain Coca Cola contain different sweeteners.
01P-0290	Jul. 2, 2001 Jan. 28, 2003	Hodgson Mill	Requests that FDA issue a definition for the term "stone ground" as applied to wheat flour. Seeks reconsideration of this request.
01P-0320	Jul. 26, 2001	Center for Science in the Public Interest	Requests that FDA propose rulemaking to establish format requirements for ingredient lists.
01P-0406	Sep. 14, 2001	The International Bottled Water Association	Requests that FDA require producers of bottled water to include telephone contact information on the labels of bottled water.
00P- 1322/CP2	Oct. 4, 2001	Center for Science in the Public Interest	Requests that FDA impose labeling requirements for allergens and establish good manufacturing practices aimed to prevent the inadvertent introduction of allergens into non-allergenic foods.
00P-1439	Oct. 10, 2001	Iceberg Industries Corporation	Requests that FDA amend the standard for Iceberg Water.
02P-0122	Mar. 22, 2002	Center for Science in the Public Interest	Requests that FDA adopt recommendations for functional foods contained in a July 2000 GAO report.
03P-0041	Jan. 31. 2003	Bunker Hill Cheese Co.	Requests that FDA permit use of the term "yogurt cheese" as a common or usual name.

		2003Q- 0401	June 23, 2003	Wellness Lifestyles, Inc. D/B/A/ American Longevity and Life Extension Foundations Buyers Club, Inc.	Requests FDA to permit a claim that consumption of omega-3 fatty acids may reduce the risk of coronary heart disease.
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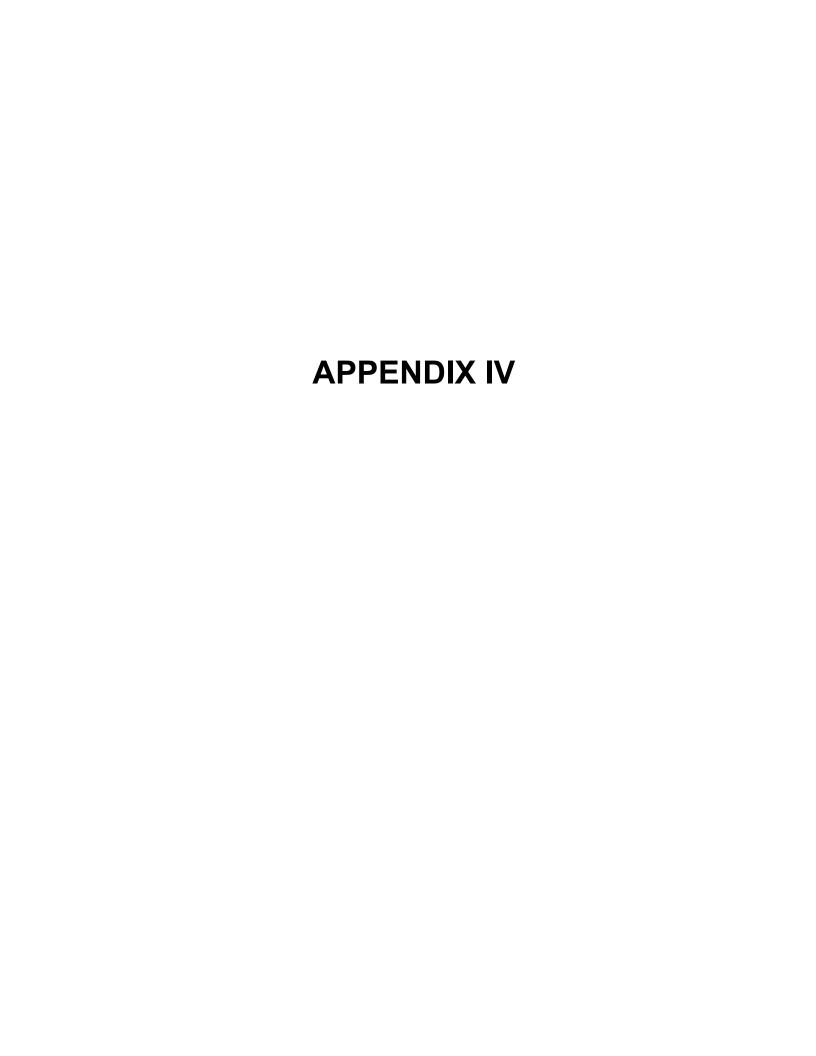
Examples of Pending ONPLDS Rulemaking Activities Appendix III

Federal Register Citation & Docket	Date	Action	Summary
58 FR 2950	Jan. 6, 1993	Advance	FDA intends to require that canned tuna with the ingredient
Docket # 90N- 361M [*]		Notice of Proposed Rulemaking	vegetable broth use the term "includes soybeans" in the ingredients list when soybeans are one of the vegetable extractives used to make the vegetable; amend the common or usual name regulations for protein hydrolysates and amend the food labeling regulations to allow and/or labeling for the declaration of
CO ED C7400	D	A al	sweeteners in soft drinks.
60 FR 67492	Dec. 29, 1995	Advance Notice of	FDA intends to review its regulations pertaining to identity, quality, and fill of containers for standardized foods and its common or
Docket # 95N-0294	1000	Proposed Rulemaking	usual name regulations for nonstandardized foods.
61 FR 29701	Jun. 12,	Advance	FDA intends to review food labeling regulations pertaining to the
	1996	Notice of	exemption for soft drinks from requirements for type size;
Docket # 96N-0149		Proposed	requirements for "statements of identity" and flavor labeling;
		Rulemaking	requirements for labeling food additives; and its infant formula regulations to ensure that they fully reflect the Federal Food, Drug, and Cosmetic Act.
61 FR 36154	Jul. 9, 1996	Proposed	FDA proposed rule to establish current good manufacturing
		Rule;	regulations, quality control procedures, quality factors, notification
68 FR 22341	Apr. 28, 2003	Extension of Comment	requirements and records and reports for the production of infant formula.
Docket # 95N-0309	2003	Period	Comment period reopened until June 27, 2003.

^{*} Dockets listed in bold relate to rulemaking proceedings that FDA intends to terminate. 68 Fed. Reg. 19,766 (Apr. 22, 2003) (Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent).

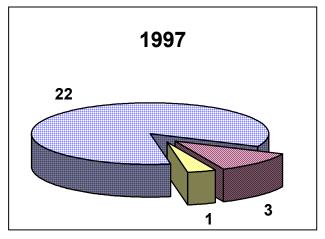
61 FR 60661 Docket # 96N-0364*	Nov. 29, 1996	Advance Notice of Proposed Rulemaking	FDA intends to reevaluate its approach to the regulation of medical foods to ensure that products are safe for their intended uses; that claims for these products are truthful and not misleading, and supported by sound science; and that labeling is adequate to inform consumers about the appropriate and safe use of such products.
61 FR Part 67243 Docket # 96N-0421 and # 94P-0453	Dec. 20, 1996	Proposed Rule	FDA proposed rule to amend its food labeling regulations to provide for the use of nutrient content claims based on the reduced availability of fat to the body because of the use of a fat substitute ingredient in the food.
62 FR 67771 Dockets # 91N-384H and 96P-0500	Dec. 30, 1997 May 8, 2002	Advance Notice of Proposed Rulemaking; Extension of Comment Period	FDA is extending until Jan. 1, 2006 the partial stay of certain provisions of the nutrient content claim regulations pertaining to use of the term "healthy." FDA needs additional time to conduct rulemaking on whether to amend the sodium content requirements for foods labeled "healthy."
63 FR 1078 Dockets # 96P- 0023 and 96P-0179	Jan. 8, 1998 Mar. 25, 1998	Proposed Rule; Extension of Comment Period	Comment period extended until May 26, 1998 on a proposed rule to amend the nutrition labeling regulations pertaining to reference amounts for "sugars and sweets."
63 FR 20147 Docket # 94P-0043	Apr. 22, 1998	Proposed Rule	FDA proposed rule to amend the regulation for crabmeat by adding Callinectes sapidus to those listed in the regulation and assigning it the common name "blue crabmeat."
65 FR 54686 Dockets # 00P-1275 and 00P-1276	Sept. 8, 2000 Oct. 5, 2001	Interim Final Rule; Comment	FDA authorized the use of health claims asserting the relationship between plant sterol/stanol esters and reduced risk of coronary heart disease.
and 001 1210	231. 0, 2001	Period Reopened	

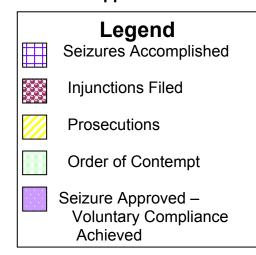
68 FR 5377	Feb. 3, 2003	Proposed	FDA proposed rule to require all domestic and foreign facilities that
Docket # 02N-0276		Rule	process, pack or hold food to register with FDA by December 12, 2003.
68 FR 39873	Jul. 3, 2003	Advance	FDA requested comments on a petition to revoke standards for low-
		Notice of	fat yogurt and nonfat yogurt and to amend standards for yogurt and
Docket #00P-0685		Proposed	cultured milk.
		Rulemaking	
68 FR 41507	Jul. 11, 2003	Advance	FDA solicited information and data that can be used to establish
		Notice of	new nutrient content claims about <i>trans</i> fat and required statements
Docket #03N-0076		Proposed	to enhance consumer understanding.
		Rulemaking	

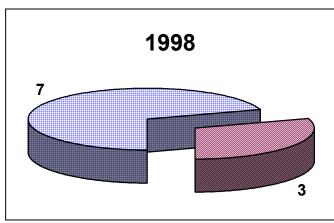


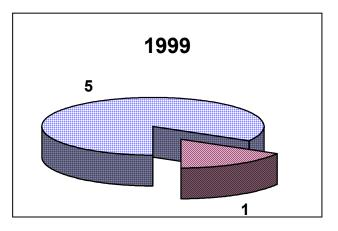
Enforcement Actions FY 1997 to FY 2001

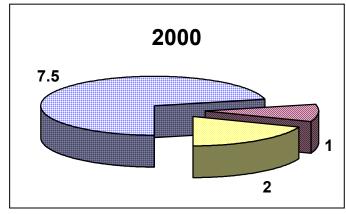
Center for Food Safety and Applied Nutrition
Appendix IV

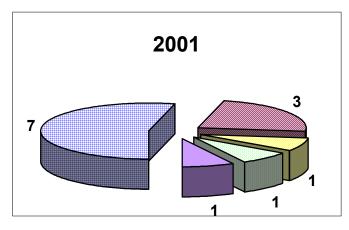












The overall number of CFSAN enforcement actions has significantly declined. As this chart shows, there were a total of 26 enforcement actions disclosed by the Agency for 1997. By comparison, in 2001 that number was half as great. Although not shown on this chart, there were 65 enforcement actions in 1994.

Source of data: Division of Compliance Policy, Division of Compliance Management and Operations, Office of Enforcement Note: Does not include Office of Criminal Investigations data.